THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUN 30 1997

The Honorable Albert Gore, Jr.
President of the Senate
Washington, D.C. 20510

Dear Mr. President:

I am respectfully submitting the final report required by section 4202 of the Omnibus Budget Reconciliation Act of 1990, P.L. 101-508, which mandated the 3-year Staff-Assisted Home Dialysis Demonstration.

This report: (a) provides background on home hemodialysis, the legislative requirements for the demonstration, and the research approach; (b) describes the efforts made to recruit facilities willing to participate and identify patients who could meet the Congressionally-mandated eligibility criteria; and (c) presents results and conclusions.

BACKGROUND

The purpose of the demonstration was to determine whether the services of home hemodialysis staff assistants for a select group of severely disabled End-Stage Renal Disease (ESRD) patients may be covered under the Medicare program in a cost-effective manner that ensures patient safety.

The law stipulated that, to be eligible for the demonstration, maintenance hemodialysis patients had to be confined to a bed or wheelchair, have a serious medical condition that would be exacerbated by travel to a dialysis facility, and be eligible for ambulance transportation to dialysis facilities. The law also specified the formula that was to be used in setting rates for home hemodialysis aide services and limited the demonstration to 800 enrollees, but stipulated that patients receiving the experimental services during the demonstration were to continue to receive the services after the demonstration ended.

Patients began receiving services in May 1992, and enrollment continued for 2 years, with patients being tracked for the third year.

An interim report was submitted to Congress on January 15, 1993.

HIGHLIGHTS

A letter of solicitation was sent to all 2,137 maintenance dialysis facilities in January 1992, and more than half responded:

- Half of the respondent facilities indicated they were not interested in participating in the demonstration because patients meeting the Congressionally-mandated eligibility criteria were either too ill to be dialyzed at home, the rates were too low, or the facility would not be able to find staff qualified to provide home hemodialysis aide services for these patients. The Congressionally-mandated rate-setting formula for rates per dialysis session for aide services was area-specific, but averaged about $50. This was paid in addition to the regular Medicare composite rate for dialysis.

- A third of the respondent facilities indicated they were interested but did not currently have patients who would meet the eligibility criteria.

- Only 13 percent (144 facilities) indicated they were interested in participating and had eligible patients.

By the end of the 2-year enrollment period, only 38 facilities with 91 patients actually participated in the demonstration. Patients were randomly assigned to an experimental group or to a control group. However, of the 46 patients who were assigned to the experimental group, only 20 patients ever received Medicare-paid home hemodialysis aide services.

Patients had to be withdrawn from the demonstration because they became too ill for home hemodialysis, were admitted to nursing homes, or died. The overall mortality rate among demonstration enrollees was 78 percent over a period of 2 years and 9 months. By contrast to the general ESRD population, that had approximately a 44 percent mortality rate over a comparable period. Although the numbers are too small for meaningful inferences, patients who received aide services had better scores on quality of care measures and a lower mortality rate.

Although all of the enrolled patients met the medical necessity criteria for ambulance use, less than one-third had been using ambulances to travel to dialysis facilities. Some of the explanation for low ambulance utilization is that most patients were served by independent dialysis facilities, and Medicare only covered ambulance use to hospital-based dialysis facilities.

It is noteworthy that 90 percent of the patients in this demonstration indicated they were satisfied with their pre-demonstration dialysis arrangements.

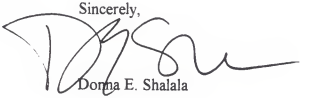
The cost of the home aide services was low because of the limited duration of experimental services. Of the 20 experimental patients who received aide services, only 4 patients were continuing to receive these services as of December 1995.

CONCLUSION

The eligibility criteria that were Congressionally-mandated for this demonstration, in general, tended to characterize patients who are too ill for home hemodialysis. As a result, a home hemodialysis aide is not likely to be a practical alternative for most patients who can meet the Congressionally-mandated eligibility criteria.

The estimated cost to prepare this report is $40,000. I am also sending a copy of this report to the Speaker of the House of Representatives.

Sincerely,



Donna E. Shalala

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

JUN 30 1997

The Honorable Newt Gingrich
Speaker of the House
of Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

I am respectfully submitting the final report required by section 4202 of the Omnibus Budget Reconciliation Act of 1990, P.L. 101-508, which mandated the 3-year Staff-Assisted Home Dialysis Demonstration.

This report: (a) provides background on home hemodialysis, the legislative requirements for the demonstration, and the research approach; (b) describes the efforts made to recruit facilities willing to participate and identify patients who could meet the Congressionally-mandated eligibility criteria; and (c) presents results and conclusions.

BACKGROUND

The purpose of the demonstration was to determine whether the services of home hemodialysis staff assistants for a select group of severely disabled End-Stage Renal Disease (ESRD) patients may be covered under the Medicare program in a cost-effective manner that ensures patient safety.

The law stipulated that, to be eligible for the demonstration, maintenance hemodialysis patients had to be confined to a bed or wheelchair, have a serious medical condition that would be exacerbated by travel to a dialysis facility, and be eligible for ambulance transportation to dialysis facilities. The law also specified the formula that was to be used in setting rates for home hemodialysis aide services and limited the demonstration to 800 enrollees, but stipulated that patients receiving the experimental services during the demonstration were to continue to receive the services after the demonstration ended.

Patients began receiving services in May 1992, and enrollment continued for 2 years, with patients being tracked for the third year.

An interim report was submitted to Congress on January 15, 1993.

HIGHLIGHTS

A letter of solicitation was sent to all 2,137 maintenance dialysis facilities in January 1992, and more than half responded:

- Half of the respondent facilities indicated they were not interested in participating in the demonstration because patients meeting the Congressionally-mandated eligibility criteria were either too ill to be dialyzed at home, the rates were too low, or the facility would not be able to find staff qualified to provide home hemodialysis aide services for these patients. The Congressionally-mandated rate-setting formula for rates per dialysis session for aide services was area-specific, but averaged about $50. This was paid in addition to the regular Medicare composite rate for dialysis.

- A third of the respondent facilities indicated they were interested but did not currently have patients who would meet the eligibility criteria.

- Only 13 percent (144 facilities) indicated they were interested in participating and had eligible patients.

By the end of the 2-year enrollment period, only 38 facilities with 91 patients actually participated in the demonstration. Patients were randomly assigned to an experimental group or to a control group. However, of the 46 patients who were assigned to the experimental group, only 20 patients ever received Medicare-paid home hemodialysis aide services.

Patients had to be withdrawn from the demonstration because they became too ill for home hemodialysis, were admitted to nursing homes, or died. The overall mortality rate among demonstration enrollees was 78 percent over a period of 2 years and 9 months. By contrast to the general ESRD population, that had approximately a 44 percent mortality rate over a comparable period. Although the numbers are too small for meaningful inferences, patients who received aide services had better scores on quality of care measures and a lower mortality rate.

Although all of the enrolled patients met the medical necessity criteria for ambulance use, less than one-third had been using ambulances to travel to dialysis facilities. Some of the explanation for low ambulance utilization is that most patients were served by independent dialysis facilities, and Medicare only covered ambulance use to hospital-based dialysis facilities.

It is noteworthy that 90 percent of the patients in this demonstration indicated they were satisfied with their pre-demonstration dialysis arrangements.

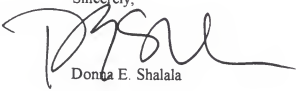
The cost of the home aide services was low because of the limited duration of experimental services. Of the 20 experimental patients who received aide services, only 4 patients were continuing to receive these services as of December 1995.

CONCLUSION

The eligibility criteria that were Congressionally-mandated for this demonstration, in general, tended to characterize patients who are too ill for home hemodialysis. As a result, a home hemodialysis aide is not likely to be a practical alternative for most patients who can meet the Congressionally-mandated eligibility criteria.

The estimated cost to prepare this report is $40,000. I am also sending a copy of this report to the President of the Senate.

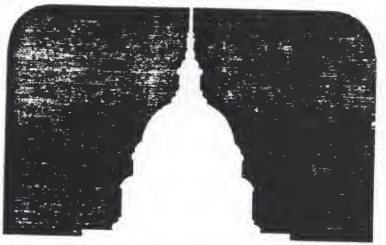
Sincerely,



Donna E. Shalala

Enclosure

Staff-Assisted Home Dialysis Demonstration



Report to Congress

U.S. Department of Health and Human Services
Health Care Financing Administration
Office of Research and Demonstrations

TABLE OF CONTENTS

STAFF-ASSISTED HOME DIALYSIS DEMONSTRATION

EXECUTIVE SUMMARY

Background

Home dialysis offers the potential to enhance the quality of life of End-Stage Renal Disease (ESRD) patients and is generally believed to be cost-effective. Most home dialysis treatment is peritoneal, which requires neither machine nor aide. Patients who are not appropriate for peritoneal dialysis require hemodialysis. Home hemodialysis requires the installation of a machine in the home and someone to assist with each dialysis session. At present, home hemodialysis aide services are not a Medicare-covered benefit; therefore, home hemodialysis aides are usually unpaid family members or friends who undergo some training for this task, or they are aides paid for by other insurers. Only 1.2 percent of ESRD dialysis patients were using home hemodialysis in 1993.

Section 4202 of the Omnibus Budget Reconciliation Act (OBRA) of 1990, P.L. 101-508, enacted November 5, 1990, mandated a 3-year demonstration to determine whether it would be safe and cost-effective for Medicare to cover the services of home hemodialysis aides or assistants for a very specific subset of disabled ESRD patients. The legislation stipulated that eligible Medicare ESRD patients: (1) be physician-certified as confined to a bed or wheelchair and unable to transfer from bed to chair; (2) have a serious medical condition as specified by the Secretary of Health and Human Services (the Secretary) that would be exacerbated by regular travel to and from a dialysis facility; (3) be eligible for ambulance transport to a dialysis facility and expected to use such services for at least 6 months, such that the ambulance cost would be expected to exceed the cost of a home aide; (4) have no family member available to assist with home dialysis; and (5) not be residents of Skilled Nursing Facilities (SNFs).

The Health Care Financing Administration (HCFA) developed the Scope of Work for a contractor to assist HCFA with the implementation and evaluation of this demonstration, and

issued a Request for Proposal in February 1991. In June 1991, an award was made to Abt Associates as prime contractor, and Urban Institute as the sub-contractor to Abt.

In May of 1991, HCFA developed the payment rates for home aide services according to the Congressionally-mandated formula, which yielded a per-session mean of $48.42 for independent facilities and $50.66 for hospital-based facilities. This payment was to be made in addition to the routine Medicare composite rate payment for each session.

Demonstration Implementation

Abt Associates sent informational materials regarding the demonstration to all 2,137 dialysis facilities in the U.S. in January 1992, asking if they were interested in participating in the demonstration and if they had potentially eligible patients. More than half responded and, of the respondents, 13 percent indicated they were interested in participating and had eligible patients; 37 percent were interested in participating but did not have eligible patients; and 50 percent were not interested in participating in the demonstration.

Of the facilities that were not interested in participating, 29 percent indicated that their patients meeting the Congressionally-mandated eligibility criteria were too ill to be dialyzed at home; 29 percent considered the payment rate to be too low; and 24 percent noted that they would be unable to find qualified staff.

All of the interested facilities were sent application materials, whether or not they had current patients to enroll. Although 144 facilities had indicated they were interested in participating and might have eligible patients, ultimately only 38 facilities with 91 patients actually participated in the demonstration.

Facilities interested in participating in the demonstration tended to be larger and had previous experience with home hemodialysis.

Patients determined to be eligible for the demonstration were randomized to an experimental or a control group, with the control group receiving whatever dialysis services would have been received in the absence of the demonstration. Facilities with experimental patients signed Provider Participation Agreements with HCFA which authorized payment for home aides under the demonstration. The provision of experimental services began on May 7, 1992.

Results

Patients were enrolled throughout a 2-year period and tracked through the third year. As expected, patients meeting the Congressionally-mandated criteria were older and sicker than the general ESRD population. However, the majority indicated they were very satisfied with their dialysis arrangements prior to the demonstration. Most traveled to dialysis facilities in vehicles other than ambulances, and those who had used home hemodialysis aides paid for by another payer were somewhat more satisfied with their pre-demonstration dialysis arrangements than those who had been traveling to dialysis facilities.

Of the 91 patients enrolled in the demonstration, 46 patients were randomly assigned to receive the experimental benefit. Of these 46, only 20 actually had home aides who were paid under the demonstration. The rest either withdrew from the demonstration, entered nursing homes, or died before receiving home aide services.

While the design of the experiment enabled considerable baseline data to be collected and analyzed, since only 91 patients enrolled in the demonstration and only 20 patients ever received Medicare-paid home aide services for dialysis, much of the planned analysis was infeasible. Many more subjects would be needed to obtain sufficient statistical power to draw valid conclusions about the safety and efficacy of home aides for this population. Despite the drawbacks of the small sample, the demonstration did yield some useful information.

Conclusions

- The eligibility criteria tended to characterize patients who are too ill for home hemodialysis. The majority of such patients were already too ill to begin dialysis outside of a facility and physicians were unwilling to enroll them or their condition worsened soon after enrollment and they had to be admitted to nursing homes or be withdrawn from the demonstration for other reasons related to their deteriorating condition or they died. The overall mortality rate among demonstration enrollees was 78 percent over a period of 2 years and 9 months, by contrast to the general ESRD population, which had approximately a 44 percent mortality rate over a comparable

period. A home hemodialysis aide is not likely to be a viable alternative for most patients who require ambulance transport to dialysis treatment.

- It is the pre-existing condition of such patients, not the receipt of paid home aide services, that is primarily responsible for their high mortality rate. Of the 46 experimental patients,

  10 patients were withdrawn from the demonstration and 12 patients died before they could receive the service. At the time data collection concluded, 4 patients were still awaiting aides and only 20 had actually received aide services. Although the numbers are too small for meaningful inferences, there were better scores on quality of care measures and a lower mortality rate among the patients who did receive home hemodialysis aides relative to experimental patients who did not receive aides, and relative to control patients.

- The cost of the home aide services was relatively low because of the limited duration during which the patient was in a condition to receive the services. The average charge per month for a home hemodialysis aide under the demonstration was $573, but the average duration for receipt of aide services was only 10 months. Of the 20 experimental patients who received aide services, only 6 were continuing to receive these services as of January 1, 1995.

Plans for Additional Analyses

Additional analyses are planned using larger data sets to explore issues that interested Congress, but could not be adequately addressed through the demonstration. These include studies of ESRD patients traveling to dialysis in ambulances (especially patients in nursing homes), and studies of ESRD patients who are high-cost outliers requiring an extensive array of costly services. Although the demonstration was unable to answer many questions because of very low numbers of enrollees, these additional analyses will address some of the important issues.

STAFF-ASSISTED HOME DIALYSIS DEMONSTRATION

1. BACKGROUND

Persons and dependents insured under Social Security have been eligible for Medicare through the ESRD program since 1973 if they have permanent kidney failure that requires routine maintenance dialysis or if they need a kidney transplant to maintain life. There are two general types of dialysis: (1) hemodialysis, in which blood from the patient's body is passed through a dialysis machine which filters out certain body wastes; and (2) peritoneal dialysis, in which no machine is required and blood is filtered within the abdominal cavity without leaving the patient's body. Hemodialysis is the most common method of dialysis, and patients usually require 3 to 4 hour-long treatments every week.

1.1 HOME DIALYSIS

Home dialysis has received a great deal of attention from Medicare policy makers and is considered by researchers, clinicians, and patients to be a modality that enhances the quality of life for many patients, while possibly lowering costs. However, home *hemo*dialysis requires the installation of a machine (and adequate water supply) in the patient's home and an assistant for each dialysis session. Most home dialysis is *peritoneal*, which requires neither machine nor aide.

Home dialysis (whether hemodialysis or peritoneal dialysis) tends to be favored by patients and clinicians for the most active and healthy ESRD patients. There has been relatively little experience with dialyzing severely disabled, medically precarious patients at home, although for some such patients home dialysis may be preferable to the stress of traveling to a dialysis facility 2 to 3 times each week.

As of 1993, approximately 29,000 patients, 17 percent of the dialysis population, used home peritoneal dialysis. Only 2,250 patients, 1.2 percent of dialysis patients, used home hemodialysis, either with the assistance of an unpaid family member or friend, or with the assistance of an aide paid by a source other than Medicare, since the services of a home hemodialysis aide or assistant are not a Medicare-covered benefit (HCFA, 1994).

When the dialysis facility has full responsibility for in-facility or in-home dialysis, the facility receives a fixed, all-inclusive payment called the composite rate for each dialysis session. This rate is the same, regardless of modality or setting, and it presumes that a certain proportion of patients will be dialyzed at home (at lower cost). The rate was intended to optimize the number of patients dialyzing at home. Although that number has increased, the increase was primarily among the patients appropriate for *peritoneal* dialysis, since this modality requires no machine or aide and is very low in cost.

1.1.1 Home Hemodialysis Payment Methods

Home hemodialysis patients can choose between two methods of payment. Under Method I, the dialysis facility receives the composite rate for each dialysis session and is responsible for providing all of the supplies and equipment that a patient needs at home; under Method II, the facility does not receive any payment for dialysis, and the patient purchases supplies and equipment directly from a supplier, with Medicare paying the supplier on the basis of reasonable charges.[1]

Under either method, a dialysis facility is responsible for providing the same support services provided for in-facility dialysis. For Method I patients, these costs are included in the composite rate; for Method II patients, the back-up dialysis facility receives a separate monthly payment of $121.15 for total home support services, e.g., social workers and dietitians. At present, most home hemodialysis is reimbursed under Method I; however, the proportion under Method II has steadily increased since 1990 to about 40 percent as of June 1996.

In October 1989, the U.S. General Accounting Office (GAO) reported that Medicare payments under Method II were much higher than under Method I. Payments to one particular supplier under Method II were approximately twice as high as Method I payments (GAO, 1990). Following GAO and HCFA investigations, OBRA 1989 limited the amount payable under Method II to no more than the amount payable under Method I effective February 1,

---

1 At the time this demonstration was created, the reasonable charge was the lowest of (1) the actual charge, (2) the customary charge by a particular supplier, or (3) the prevailing charge. The prevailing charge was defined as the 75th percentile of customary charges for similar items in the local area.

1990, and soon after, this supplier discontinued home aide services for 1,553 ESRD patients. HCFA found alternative arrangements for these patients, including paying the home aide costs for a few patients for whom no alternative arrangements were possible. The legislation authorizing the Staff-Assisted Home Dialysis Demonstration specified that the few patients remaining with HCFA-paid home hemodialysis aides were automatically eligible for the demonstration benefits, i.e., "grandfathered" into the demonstration.

1.2 Legislation Authorizing the Demonstration

In 1990, section 4202 of OBRA 1990, P.L. 101-508, mandated a 3-year demonstration to determine whether the services of home hemodialysis staff assistants, for a subset of disabled ESRD patients, can be covered under Medicare in a cost-effective manner while ensuring patient safety (see Appendix A).

1.2.1 Legislative Requirements

Although the legislation limited benefits to no more than 800 patients, it also established a detailed, rate-setting method, and contained very specific eligibility criteria. The latter constraints yielded a very small, select group of patients for study.

Congress also specified that any patients enrolled in the demonstration and receiving those benefits at its end may continue to receive Medicare-reimbursed home aides under the same payment provisions for the duration of their lives, so long as they continue to meet the eligibility requirements.

Patients who received home aide services under the demonstration had to be eligible for Medicare under the ESRD program. Furthermore, they were required to:

(a) be physician-certified as confined to a bed or wheelchair and unable to transfer from bed to chair;

(b) have a serious medical condition (as specified by the Secretary of Health and Human Services (the Secretary)) that would be exacerbated by regular travel to and from a dialysis facility (see page 9);

(c) be eligible for ambulance transport to a dialysis facility and expected to use such services for at least 6 months, such that the ambulance cost would be expected to exceed the cost of a home aide;

(d) have no family member available to assist with home dialysis; and

(e) not be residents of Skilled Nursing Facilities (SNFs).

Home aides providing demonstration services had to meet minimum qualifications specified by the Secretary and any applicable qualifications under state law. Services specified in the demonstration legislation included technical assistance with the operation of a hemodialysis machine and care of the patient during home hemodialysis. The latter service included "administration of medications to maintain the patency of the extracorporeal circuit," which is generally interpreted to mean the intravenous (IV) administration of anti-coagulants.

Payments for aides were to be per treatment and prospectively determined by the Secretary, using the following formula:

- The payment amount was the product of a rate and an area wage adjustment factor.
- The rate was equal to the *difference between*:
  (a) two-thirds of the labor portion of the composite rate (adjusted to reflect differences in area wage levels); and
  (b) the product of the national median hourly wage for a home hemodialysis staff assistant and the national median time expended in the provision of home hemodialysis services (taking into account travel time and pre-dialysis patient care).
- The national median hourly wage was the sum of 65 percent of the national median hourly wage for a Licensed Practical Nurse (LPN) and 35 percent of the national median hourly wage for a Registered Nurse (RN).
- The national median hourly wage and the national median of the average time expended for these services were determined annually on the basis of the most recent data available.

In addition, payment was subject to the usual 80 percent reimbursement (with patients or other payers being responsible for the 20 percent copayment). Facilities supplying home aides received this payment as an add-on to the composite rate; therefore, all experimental patients in the demonstration had to be Method I home hemodialysis patients.

Statutory funding for the demonstration from the Supplementary Medical Insurance trust fund was set at a $14 million maximum:

- $4 million maximum for FY 1991;
- $4 million maximum for FY 1992;
- $3 million maximum for FY 1993;
- $2 million maximum for FY 1994; and
- $1 million maximum for FY 1995.

1.3 Demonstration Design

The demonstration was designed as a randomized experiment at the individual patient level. Enrolled patients were randomly assigned on a 50/50 basis to 2 groups. One group was designated experimental and was to receive the demonstration benefit of a Medicare-covered home hemodialysis aide, while the control group did not receive this benefit but continued with its previous dialysis and transportation arrangements. Facilities enrolling two or more patients had their patients equally divided between experimental and control groups.

The few remaining patients who had been receiving Medicare-covered home hemodialysis assistants since 1990 (see 1.1.1) were moved to coverage under the demonstration. They were automatically enrolled on a "grandfathered" basis without having to meet the same eligibility criteria. Thus, they were not part of the experimental analysis of home aides.

1.4 Research and Evaluation Approach

A total of 91 beneficiaries enrolled in the demonstration and 46 were randomly assigned experimental status. Of the 46 experimentals, only 20 ever received any home aide dialysis services. The balance either died or withdrew before having a home aide assigned. The small sample made much of the planned analysis infeasible. Many more subjects were

needed in order to obtain sufficient statistical power to draw valid conclusions about the safety and efficacy of home aides for this population. Therefore, the analysis is confined to the use of descriptive data, since the small numbers preclude measurement of statistical significance.

1.4.1 PRIMARY DATA

Primary data collected for the evaluation included:

- Demographic and medical history data obtained by the ESRD networks from the medical records of all experimental and control patients when they enrolled in the demonstration.

- Clinical monitoring data obtained by the ESRD networks from the medical records of all experimental and control patients every 6 months throughout the course of the demonstration.

- Functional status, quality of life, and patient satisfaction data obtained through Abt Associates' telephone surveys with all experimental and control patients, when they entered.[2]

- In-depth telephone interviews (case studies) with a sample of participating and non-participating dialysis facilities, conducted by Abt Associates and The Urban Institute several months after the demonstration began.

- Data in regard to the education, credentials, years of experience, and travel time and distance of the home hemodialysis aide.

---

2 A follow-up survey was planned 1 year after enrollment, but was canceled when it became clear that there were not sufficient subjects for meaningful and statistically valid analyses.

Copies of the medical record abstraction form and the telephone survey form are in Appendix B.

Medical Record Data

Medical record data were collected to serve three purposes. First, measures of illness severity and risk factors add to the capacity of the analysis to distinguish the influence of the experimental therapy from that of other factors known to affect patient outcomes and cost. Second, other clinical measures describe the care given, including number of dialysis sessions, dialyzer type and bath used, reuse of dialyzer, type of vascular access, use of erythropoietin (EPO), and direct measures of the extent of dialysis delivered. Third, clinical measures serve to supplement measures of outcomes, such as patient morbidity and hospital use, which are available from HCFA data systems. Sections 3.2.3 and 3.3.3 below describe findings from the medical record data.

Beneficiary Surveys

There were a number of questions about paid home aides for this study population that could not be addressed through claims data or clinical data. Many of these issues were addressed with the survey of the demonstration's beneficiaries. However, again due to low participation, effects of paid aides could not be investigated since only 20 patients were actually assigned home aides and there were fewer than 100 enrollees. Nonetheless, surveys were completed with many of the enrollees or their proxies.

The baseline survey was conducted by telephone among all demonstration patients, both experimental and controls, over the course of 2 years as participants enrolled. This survey asked about dialysis care and transportation during the previous year, functional and psychological status during the previous year and the previous month, and reasons for deciding to enroll in the demonstration. A follow-up survey 1 year after enrollment was planned, with additional questions for experimental patients about their experience with the Medicare-paid home aide. However, due to the low number of patients who enrolled and received paid aides, this part of the survey was not executed. Section 3.2.4 below describes the key findings from this survey.

Facility Case Studies

The beneficiary surveys gathered information on patients and their reasons for participating in the demonstration. It was also necessary to gather information from dialysis facilities about their reasons for deciding for or against participation, especially since there was such low participation.

Abt Associates and The Urban Institute undertook a series of exploratory interviews with 3 of the largest kidney dialysis facilities in each network (Total = 53). The main goals of the telephone interviews were to explore the reasons facilities chose not to enroll patients in the demonstration, and to obtain their views on the design of the demonstration and on paying aides for home hemodialysis in general. Section 3.1.2 below describes findings from these facility case studies.

Home Hemodialysis Aide Data

Facilities with patients assigned to the experimental group were sent a form to be filled out for every patient-aide combination. The form provided information in regard to: the aide's education and credentials, years of experience in dialysis and years of experience as a home-dialysis aide, and the aide's usual travel time and distance from point of origin to patient's home and from patient's home to aide's destination. Facilities provided this information for 17 of the 20 patients who received aide services. Section 3.3.2 below provides information in regard to the home hemodialysis aide data.

1.4.2 Secondary Data

In addition, a variety of secondary data sources was utilized to compare demonstration enrollees with the ESRD population as a whole:

- Program Management and Medical Information System (PMMIS). The PMMIS data consists of Medicare ESRD patients' records and has data from HCFA special purpose forms such as the Medical Evidence Form and the Transplant Follow-up form.

- U.S. Renal Data System (USRDS). The USRDS database is composed of HCFA PMMIS data residing on a relational database at the University of Michigan (the database formerly resided at The Urban Institute). The data are verified and "filtered" for validity, and are easily "queried."

- Special USRDS Survey Samples. These data are formed from a 1989 national sample of the medical records of over 4,000 hemodialysis patients.

- Medicare Beneficiary and Claims Data.

For each of the secondary data sets, patient records for late 1992, 1993, and early 1994 were used.

2. Demonstration Implementation

The demonstration began on April 1, 1992. HCFA had previously contracted with Abt Associates to provide technical assistance with implementation and with analyzing evaluation results. Abt has been assisted by The Urban Institute. HCFA also developed a special contractual relationship with the 18 regional ESRD networks to assist with eligibility review, quality assurance, and data collection activities throughout the course of the demonstration.

2.1 Solicitation And Enrollment of Participants

The provider and patient enrollment process is illustrated in Exhibit A. Provider invitation/solicitation materials were mailed to all 2,137 dialysis facilities nationwide between January 3 and January 7, 1992. Included in this mailing were 18 corporate headquarters, 5 facilities who still served the remaining 7 grandfathered patients, and 45 Veterans Administration facilities. In addition, a Summary Fact Sheet was sent to all dialysis facilities to explain the goals of the demonstration, the criteria for participation, the process, and the payment (see Appendix C).

Dialysis facilities were asked to return a Facility Interest Form indicating whether they were interested and thought they had eligible patients, were interested but did not currently

Exhibit A

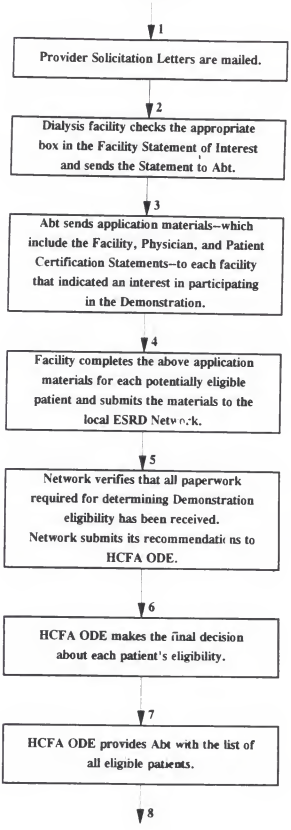
Implementation & Evaluation

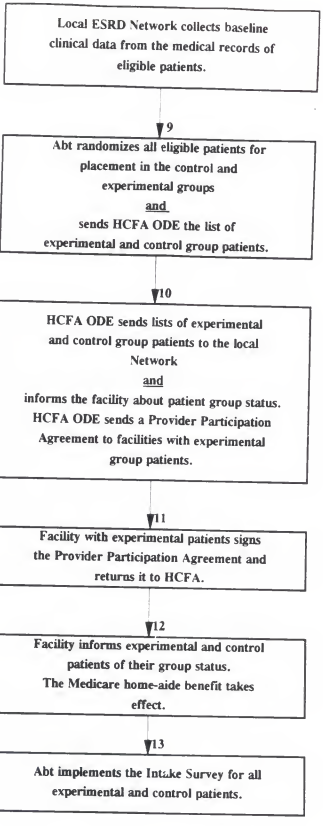
of the

Staff-Assisted Home Dialysis Demonstration

PROVIDER AND PATIENT ENROLLMENT PROCESS

January 1992




Local ESRD Network collects baseline clinical data from the medical records of eligible patients.
9
Abt randomizes all eligible patients for placement in the control and experimental groups
and
sends HCFA ODE the list of experimental and control group patients.
10
HCFA ODE sends lists of experimental and control group patients to the local Network
and
informs the facility about patient group status.
HCFA ODE sends a Provider Participation Agreement to facilities with experimental group patients.
11
Facility with experimental patients signs the Provider Participation Agreement and returns it to HCFA.
12
Facility informs experimental and control patients of their group status.
The Medicare home-aide benefit takes effect.
13
Abt implements the Intake Survey for all experimental and control patients.

have eligible patients, or were not interested. Those expressing interest in participating were mailed an application regardless of whether they thought they had any immediately eligible patients.

2.2 Eligibility Criteria

The application packet for the demonstration was developed to ensure all of the eligibility criteria were met (See Appendix D). The legislation had specified that enrolled patients must have "a serious medical condition (as specified by the Secretary) that would be exacerbated by travel to and from a dialysis facility." HCFA used an existing ESRD advisory group, the ESRD Expert Panel, to develop a list of these conditions, and this checkoff list of "Qualifying Medical Conditions" became part of the Physician Certification Statement in the application packet. This requirement did not seem to hamper enrollment. However, three other criteria posed formidable barriers to patient entry: specifying that these patients had to require ambulance services, be bed- or wheelchair-bound, and not be residents of nursing homes.

2.2.1 Ambulance Use

The specification that ambulance services were required and expected to continue for 6 months, such that ambulance costs would likely exceed home aide costs, was particularly problematic. HCFA analyses (Eggers, 1990) estimated that few ESRD beneficiaries actually use ambulances heavily: only 1.7 percent used over $5,000 in ambulance services in 1987. The top 5 percent of ESRD ambulance users 7 years ago each cost the program $6,500 or more annually, which is somewhat less than what many home aides were expected to cost. A prior survey of dialysis patients found that less than 1 percent arrived at dialysis units via ambulance (Urban Institute, 1985). In addition, ambulance use and costs vary by state, implying that Medicare carriers and fiscal intermediaries may interpret coverage guidelines differently.

Medicare has two criteria for ambulance transport to dialysis: it must be medically necessary, and the dialysis facility must be hospital-based. Since the majority of dialysis facilities are not hospital-based, a strict interpretation of the Congressional criterion would

have precluded most dialysis facilities from participation in the demonstration. Therefore, HCFA required only that patients meet the medical necessity criterion for ambulance use; the destination requirement did not have to be met.

However, the fact that Medicare does not pay for the ambulance transport to independent facilities meant that, in many cases, the patient was not using an ambulance for that reason alone. Several of these patients met all the other eligibility criteria, but their physicians were unwilling to assess whether they theoretically would have met Medicare's "medical necessity" criterion for ambulance use, had the destination not precluded Medicare payment.

2.2.2 Bed/Wheelchair-Bound

Only a small minority of ESRD patients are confined to bed or wheelchair and unable to transfer independently. During 1986, HCFA data identified about 8,000 ESRD patients who had at least some charges for wheelchair-related items (Urban Institute, 1991), but the number is probably larger since wheelchair equipment could have been bought in the past or been paid for by another source. These 8,000 ESRD patients with wheelchair charges were not all hemodialysis patients, although it was presumed that the majority would require this modality. According to HCFA's Bureau of Data Management and Strategy (BDMS), there were approximately 80,000 hemodialysis patients at the end of 1986; therefore, the 8,000 at most represented 10 percent of the hemodialysis population.

The overlap between ambulance users and wheelchair users, as identified through HCFA data, was exceedingly small.

2.2.3 Residence in Skilled Nursing Facilities

Although data was not available (see 4.1), staff in a number of dialysis facilities claimed that, in their experience, patients in the precarious condition the demonstration criteria imply were more likely to be residing in SNFs than were other ESRD patients, and SNF patients were more likely than other patients to arrive at dialysis via ambulance transport. The prohibition against enrolling SNF patients appeared to eliminate a substantial proportion of the ESRD patients who might have met all the other demonstration eligibility criteria.

2.3 Payment Rate for Aides

HCFA developed the payment rates for the demonstration using the method detailed in the legislation, which stipulated that the aide had to be able to administer anti-coagulants intravenously. Some State Nurse Practice Acts restrict IV administration to RNs (if payment is involved), yet the rate-setting formula in the law mandating the demonstration factored in the RN wage at 35 percent, and the LPN wage at 65 percent. This meant that, in areas where the participating dialysis facility would have to hire an RN as a home hemodialysis aide, it was unlikely that the rate would be sufficient to pay an RN for this service.

The formula yielded payment rates for independent and hospital-based facilities in each of the 383 Metropolitan Statistical Areas. In 1992, these rates ranged from $43.06 for independent facilities and $45.05 for hospital-based facilities in areas with the lowest wage index, to $69.26 for independent facilities and $72.46 for hospital-based facilities in areas with the highest wage index. The mean was $48.42 for independents and $50.66 for hospitals. This was the available payment to cover home-aide costs, in addition to the usual Medicare composite payment rate.

The facility also received a one-time $200 payment for training any aide-patient pair for home hemodialysis, beyond the $20 per session fee that HCFA normally pays when unpaid aides are trained.

Informal estimates from provider associations suggested that only 200-300 hemodialysis patients nationally met the stringent eligibility criteria for this demonstration, were stable enough for home hemodialysis, and could be home-dialyzed with non-RN aides. Despite these barriers, continued effort was made to have the greatest level of participation in the demonstration.

2.4 Outreach

Numerous efforts were made to educate and inform providers and patient communities of the demonstration. Table 1 shows that substantial pre-demonstration efforts were taken to inform dialysis facilities and the entire renal community of the demonstration. Even after the demonstration began, newsletters were periodically sent to the ESRD networks asking them to urge facilities to participate. Personal calls were placed to facilities that seemed interested and

Table 1: Timing of Communications on Demonstration with Renal Communities: Educational and Outreach Efforts

Summer 1991	HCFA distributed to 11 ESRD patient and professional organizations a protocol/process paper providing background on the demonstration and indicating the intended methods that were to be used.
Summer 1991	Initial HCFA meetings with affected renal communities and providers.
Oct., 1991	Urban Institute staff made a presentation regarding the demonstration at the annual meeting of the National Renal Administrators Association.
Oct., 1991	Abt Associates staff and consultant made a similar presentation at the annual meeting of the American Association of Kidney Patients.
Jan, 1992	Initial solicitation letters from HCFA to all US dialysis facilities were mailed by Abt Associates.
May 1992-varying intervals thereafter	HCFA newsletter from HCFA Project Officer to ESRD Networks concerning demonstration.
Sept.-Nov. 1992	Follow-up telephone calls to dialysis facilities which had not referred patients for the demonstration, but had initially indicated they were interested and had eligible patients.
Mar-April 1993	Further outreach to 40 Ren Dialysis Centers which had indicated corporate interest in the demonstration; special mailing to the 400 dialysis facilities currently offering home hemodialysis support services.

might have patients to enroll but had not responded, and presentations about the demonstration were made to groups.

HCFA undertook a special mailing to the 400 dialysis facilities currently providing home hemodialysis services (with aides unpaid or paid by a payer other than Medicare), since this factor appeared to be a major predictor of facility willingness to participate in the demonstration. Letters were sent to both the facility administrator and the medical director, with the latter asked to share the information with the facility's social worker, since social workers appear to have knowledge of transport difficulties.

Despite the best efforts of HCFA, Abt Associates, and The Urban Institute, enrollment levels never reached the number needed to conduct a careful evaluation. In all, 91 patients entered the demonstration (see Appendix E). Enrollment in the first month was the highest and accounted for more than 25 percent of the patients in the entire 2-year demonstration (see Exhibit B). The first 3 months resulted in 42 subjects altogether, almost half of the 91 patients who eventually enrolled. Despite continuous efforts by HCFA and its contractors to increase enrollment, over the following 22 months only 49 more patients enrolled, a rate on average of 2.2 patients a month. June 1993 did see 10 patients enrolling, which might have been due to additional outreach conducted in the spring of 1993. Nonetheless, it is clear that after an initial surge in enrollment, the number of patients joining the demonstration dropped and continual outreach efforts never returned the rate to a comparable level. Reasons for the lack of response are discussed in further detail later in this report.

3. RESULTS

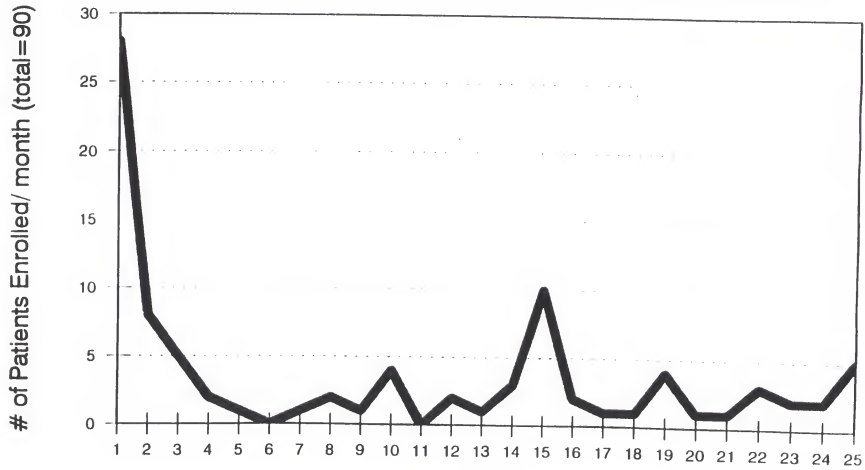
By the end of the demonstration in April 1994, enrollment had reached only 94 patients, including 3 of the 7 surviving patients who had been "grandfathered" in, leaving a total of 91 randomized patients to study. Of these, 46 patients had been assigned to the experimental group, but only 20 had received aides. Ten experimental patients had been withdrawn from the demonstration and 12 had died before they received aides; 4 were awaiting aides at the time data analysis began.

Low numbers precluded in-depth statistical analysis. A descriptive analysis is, however, given below.

Exhibit B:

Patient Enrollment by Month

Most Demonstration Patients Signed Up Early



Note: month 1 began April 1992

3.1 Facility Interest

Even before enrollment began, most facilities indicated no interest in participation for various reasons. The response data analyzed and presented in this report are based on more than half (52 percent) of the dialysis facilities having responded to the initial provider solicitation mailing.[3] This response rate is surprisingly high for a single solicitation letter. Also, it appears that respondents were not significantly different from non-respondents, in terms of facility characteristics, characteristics of patients, or the demography of the units' immediate environs.

Table 2 provides summary information regarding the responses on the Facility Interest Forms. Only 13 percent of responding facilities (144) said they were interested in participating in the demonstration and possibly had patients to refer for eligibility review. Almost 3 times as many, approximately 37 percent (418 facilities), said they were interested in participating in the demonstration but did not currently have eligible patients. Half of the facilities (568) were not interested in participating in the demonstration.

The greatest predictors of facility participation appear to be size, as shown by various measures, and experience with home dialysis. As Table 3 illustrates, facilities interested in participating tended to be larger, have more total patients, and more home patients (hemodialysis and peritoneal) -- both in absolute numbers and as a percent of total patients -- than facilities that were not interested in participating. No clear differences appear by payment amount, area wage index, or most other factors. Also, every ESRD network had some respondents in each category of interest or lack of interest.

Although rural dialysis facilities might be expected to have more patients with transportation problems, this does not appear to have translated into increased interest in the demonstration among rural facilities.

Facilities indicating they were both interested in this demonstration and had patients they believed to be eligible -- in contrast to the facilities interested but having no eligible

---

3 Included among this group of respondents were 45 facilities that had been inadvertently omitted from the initial mailing list (these were generally new facilities or branches of existing facilities). These providers were added to the mailing list, thus increasing the total target "pool" of dialysis facilities from 2,137 to 2,182.

Table 2
FACILITY RESPONSES

Response	Facilities		
	Number	% of Total Respondents	% of Facilities Nationwide
Interested in participating, current patients ready to enroll	144	13%	6.6%
Interested in participating, no current patients ready to enroll	418	37%	19.2%
Not interested in participating	568	50%	26.0%
No response	1052	-	48.2%
TOTAL	2182	-	100.0%

Source: Abt Associates' compilation of facility responses to solicitation materials.

Table 3
Characteristics of Units
Based on Response to
Home Hemodialysis Demonstration

Number of Dialysis Stations and Number of Patients at Unit

Response Status of Unit Reason for Non-Participation*	Count, Total (n)	Count, Matched to 1990 Facility Survey (n)	Mean Number of Dialysis Stations (n)	Mean Number of Patients Treated at End of 1990 (n)							
				Home Hemo-dialysis	Home Peri-tonael	Total Home	Home Patients as a % of Total Patients	Total In-Unit	TOTAL	Transient	Non-Medicare
Interested with eligible patients	144	126	15.0	4.3	15.6	19.9	23.2	66.0	85.9	15.6	6.0
Interested but no eligible patients	418	384	15.3	1.2	12.3	13.4	18.0	61.1	74.5	19.8	5.1
Not Interested	568	516	12.9	0.6	8.5	9.1	15.5	49.8	58.9	13.9	4.1
Not cost effective/insufficient staff	247	231	14.1	0.9	9.9	10.7	16.1	56.1	66.8	15.1	4.5
Not certified/don't treat home hemo patients	176	156	10.7	0.1	5.4	5.5	12.4	36.8	44.3	15.1	3.3
Lac. of patient demand/no patients eligible	166	169	13.9	1.6	9.4	10.5	16.5	52.9	63.3	14.1	4.4
Home setting inadequate/liability	27	25	13.4	0.5	10.3	10.8	17.3	51.5	62.3	12.0	4.3
State regulation/Nurse Practice Act barriers	42	39	17.2	0.9	13.6	14.5	15.8	77.6	92.1	15.3	8.9
Other**	76	63	9.3	0.1	5.8	6.0	16.6	30.1	36.1	14.1	2.9
No reason provided	31	29	13.0	0.9	10.2	11.2	18.6	48.8	59.9	12.0	3.2
No response	1052	951	12.9	1.1	9.2	10.3	17.3	49.1	59.3	14.2	4.7
TOTAL	2182	1977	13.5	1.2	10.0	11.2	17.5	52.7	63.9	15.3	4.7

Source: Urban Institute/Abt Associates collaboration on HCFA project #500-87-0030-D09. Units contacted for the demonstration were linked with data from the 1990 Facility Survey.

*More than one reason was cited for many units.

**Among units included in the 'Other' category, many indicated the reason for non-participation as one of the following: Method II provider only; transplant center only; pediatric facility; VA facility.

patients and the facilities not interested -- were located in more densely populated, poorer areas with larger minority populations, older populations, and slower population growth.

3.1.1 Reasons for Non-Participation

Almost 94 percent of the respondents who were not interested in participating gave reasons. Table 4 displays the range of responses that facilities gave for declining participation. Also, there were a number of phone calls and letters from facility administrators in which they explained at greater length their reasons for not participating as well as their overall concerns about the demonstration. A summary of the more frequent reasons for nonparticipation follows.

Inappropriate Eligibility Criteria

Many facilities reported that the very ill, severely disabled patients characterized by these eligibility criteria are not appropriate for home hemodialysis since their condition is likely to be unstable during dialysis.

Several noted what one described as a "Catch 22" situation, in that patients with conditions that would allow them to meet certain criteria would, by definition, have difficulty meeting some of the other criteria. For example, patients requiring ambulances or with medical conditions exacerbated by travel tend to be patients who cannot dialyze in a medically-unsupervised setting, and patients who are bed-bound and have no family member to assist them are likely to be residing in nursing homes. Some noted that the most appropriate patients for this demonstration are those residing in SNFs, but these patients were specifically excluded from the demonstration.

Inappropriate criteria and the dearth of patients who could meet them were cited by 163 facilities (29 percent of non-participants) as being reasons for non-participation.

Low Payment Rate

The number of facilities responding that the payment rate was too low was equal to the number responding that the patient eligibility criteria were inappropriate (see Table 4).

Table 4
Reasons for Non-Participation

Non-Participating Facilities Mentioning This Reason*	Number	Percent
No patients meeting eligibility criteria/inappropriate eligibility criteria	163	28.7
Payment too low/not cost-effective	163	28.7
Facility does no *home* hemodialysis/not certified to provide home hemodialysis/refers all home hemodialysis patients elsewhere/has no home hemodialysis patients	145	25.5
Insufficient or inadequate staff available/unable to find or hire new qualified staff	135	23.8
State regulation or Nurse Practice Act barriers	42	7.4
Acute inpatient facility only/does not provide chronic or outpatient dialysis	24	4.2
Program does no *hemodialysis*/refers all hemodialysis patients elsewhere/peritoneal dialysis only/not certified to provide hemodialysis	22	3.9
Lack of demand or patient interest	20	3.5
Home setting not safe for type of patient specified/inadequate staff supervision/quality of care inadequate	19	3.3
Pediatric facility (rarely has patients without available family)	12	2.1
Medical or financial liability concerns	9	1.6
(Ineligible) Veterans Administration facility	7	1.2
Facility is Method II provider only	4	0.7
Transplant center only, no dialysis	2	0.3
No reason given	31	5.5
Other	53	9.5

* Percentages do not sum to 100% because most facilities mentioned more than one reason for non-participation

Some reasons for non-participation may reflect different perspectives on a common issue. For example, the 163 facilities (29 percent of non-participants) who felt the payment was too low could be implying that the payment was too low to hire the kind of aide needed for these very ill patients (e.g., LPNs or RNs). Theoretically, if the payment was high enough, staff with appropriate credentials could be employed.

State Nurse Practice Acts

The demonstration legislation specified that aides must be able to administer medications that "maintain the patency of the extra corporeal circuit," i.e., to inject the anti-coagulant into the line that connects an ESRD patient to a hemodialysis machine. The legislation also stipulates that the aide must meet any "applicable qualifications" specified in state law.

Forty-two facilities in 15 states indicated that, in their states, regulations or laws such as State Nurse Practice Acts posed a barrier to their participation in the demonstration. This suggests that the facilities interpreted the state law to mean an LPN or RN, rather than a dialysis technician, would be required and, therefore, they could not afford to offer the services.

No Home Hemodialysis Services

A substantial number of facilities (26 percent of non-participants) say they do not offer home hemodialysis support services and/or are not certified to provide home hemodialysis. The Federal certification requirements (and more rigorous requirements in a few states) include having social workers or dietitians make periodic home visits to patients and having periodic home assessments of water treatment. HCFA waived the requirement of this certification for the demonstration, but those without this previous experience were uncomfortable with undertaking this new service, especially with unstable patients.

Although 1991 HCFA'S BDMS data indicated that 46 percent of dialysis facilities had home hemodialysis programs, an informal survey undertaken by The Urban Institute found that a substantial proportion of these programs were not active in 1992.

Ambulance Eligibility and Alternative Transportation

Of the 562 facilities (50 percent of respondents) wishing to participate in the demonstration, 418 (76 percent of interested facilities) did not have eligible patients. The eligibility criterion that appeared to be most problematic was the medical need for ambulance transport. HCFA was willing to accept a physician's attestation that a patient was appropriate for ambulance transport to dialysis, even if the patient was not currently traveling to dialysis via ambulance. Several facilities commented that physicians will not sign a statement that a patient needs an ambulance for safe transportation if that patient is not currently using one, because this implies that their patients are not getting necessary services and are traveling to dialysis units in a manner that could endanger their health.

3.1.2 Telephone Follow-up in Regard to Nonparticipation

Telephone interviews were conducted for follow-up purposes. These involved three distinct categories of dialysis facilities: (1) "Not Interested" (facilities that initially responded they were not interested in participating); (2) "No Response" (those that failed to respond to the initial mailing); and (3) "Interested, but no eligible patients" (facilities that initially expressed an interest in participating if they had patients who met all of the eligibility requirements). The interview was directed to either the facility administrator or the medical director.

The interviews covered seven general topic areas including the respondent's knowledge about the demonstration and its rules, reasons for not enrolling patients, other circumstances under which facilities might have participated, past or present experience with paid home hemodialysis aides, and whether respondents believe that staff-assisted home hemodialysis should be a Medicare-covered benefit.

Four significant lessons were learned:

(1) The patient group the Congress specified may not be well-suited to home hemodialysis, even with a paid aide. Many respondents felt these patients are most safely dialyzed in-unit, not at home, and at a minimum would require an RN for home care. Even with an RN, many respondents expressed concerns in regard to patient safety and the unusual degree of responsibility (and risk) aides would be assuming when caring for such ill persons in the home setting.

(2) The reimbursement offered under the demonstration was widely perceived to be inadequate. Facilities did not feel able to hire RNs at the demonstration payment rate, and were not willing to use LPNs or dialysis technicians for patient safety reasons. In addition, the cost-effectiveness of using an RN to care for a single patient at home was questioned by many respondents, who have difficulty hiring and retaining dialysis-experienced RNs for in-unit work where they can care for several patients at one time.

(3) A single mailing directed only at facility administrators with copies for medical directors was probably not the most effective method for informing the industry about the demonstration. Those most likely to advocate for the benefit for individual patients are the physicians (medical directors), nursing, and social work staff. In addition, administrative staff seem to experience a high degree of turnover and mobility. This may be less true of medical directors. Had HCFA addressed a mailing towards individual medical directors along with administrators, the response might have been more substantial.

(4) The transportation difficulties experienced by some patients would not really be solved by offering to treat them at home. Rather, directly solving the transportation problems made more sense to many respondents.

3.2 ENROLLMENT

Nationally, there are over 142,000 hemodialysis Medicare patients of whom 2,250 use home hemodialysis, with the remainder using center-hemodialysis (HCFA, 1994). Projections made earlier in the demonstration indicated that the stringent criteria of the demonstration would limit the eligible pool. Enrollment levels were expected to be between 200-300

patients. However, actual enrollment over 2 years was 91 patients, less than half the predicted amount.

The demonstration encompassed more than 2 years over which eligible patients were allowed to enroll at any time. Almost half of the 91 patients enrolled in the first 6 months, and only 16 percent enrolled in the last 6 months (Table 5).

3.2.1 Geographic Concentration

Fourteen of the 18 ESRD networks had at least one patient enrolled (Table 6); however, enrollment was geographically concentrated. Two networks, 4 and 5, accounted for almost half of the enrollees, but these two networks comprise only 10 percent of ESRD Medicare patients. Interestingly, both networks (4 and 5) are mid-Atlantic areas adjacent to the Washington DC-Baltimore region. Furthermore, 1 particular physician, affiliated with 3 facilities in the Philadelphia area (network 4), and a strong advocate of home hemodialysis, enrolled 12 (13 percent) of the 91 patients. Enrollment in the demonstration was also heavily concentrated by facility; the vast majority of facilities (98 percent) did not participate.

The four networks that had no enrollment (1,6,9,17) were in New England, the southeast (GA, NC, SC,) the Ohio region (IL, KY, OH), and northern California. These networks represent a large share of the ESRD population.

3.2.2 General Characteristics of Demonstration Enrollees Compared to ESRD Dialysis Population

Tables 7 and 8 contrast the demonstration's enrollees with the ESRD dialysis population in terms of demographic, social, and disease characteristics..

Given the demonstration's intent to help only the very sick, it is not surprising that the enrollees in the demonstration were somewhat older and much sicker. Demonstration enrollees were about 7 or 8 years older (and as a result, more likely to be female), but were comparable to the general dialysis population in having had ESRD for only 2 or 3 years. However, demonstration enrollees had much higher rates of diabetes as the primary cause of

Table 5: Summary of Demonstration Enrollment and Outcomes

Few patients enrolled from a limited number of facilities, many died and few received aides.

No. of Patients	No. of Networks	No. of Units	No. Withdrew	No. Died	No. Alive	No. of Experi-mentals	No. of Controls	No. Who Used a Paid Aide	Date of Enrollment	(#)	(%)
91	14	38	14	60	17	46	45	21	4/92-9/92:	45	49
	(of 18)	(of 2347)	(of 91)	(of 91)	(of 91)	(of 91)	(of 91)	(of 46)	10/92-3/93:	10	11
	78%	2%	15%	66%	19%	51%	49%	47%	4/93-9/93:	22	24
									10/93-4/94:	14	16

Table 6:Distribution of Demonstration Enrollees by ESRD Networks

Most Networks Participated but a few had most of the enrollment

Network	No. of Facilities	No. Enrolled	% Enrolled
1	0	0	0.00%
2	2	4	4.44%
3	1	1	1.11%
4	5	29	32.22%
5	6	15	16.67%
6	0	0	0.00%
7	3	3	3.33%
8	1	4	4.44%
9	0	0	0.00%
10	2	4	4.44%
11	1	1	1.11%
12	3	4	4.44%
13	2	7	7.78%
14	1	1	1.11%
15	6	10	11.11%
16	3	4	4.44%
17	0	0	0.00%
18	3	3	3.33%

Table 7: General Characteristics of Demonstration Enrollees vs. ESRD Dialysis Population

	Gender		Race (%each)			Age (Years)		Years Since Kidney Failure		Cause of Renal Failure (% each)			
	%M	%F	White	Black	Other*	Mean	Median	Mean	Median	Diabetes	Hypertension	Glomerulonephritis	Other
Demonstration Patients (N=84)**	46.4	53.6	61.9	35.7	2.4	65.7	70.2	3.2	2.2	41.7	23.8	10.7	22.9
All ESRD Dialysis Patients as of 12/31/91 (N=143,360)***	52.4	47.6	59.7	35.3	5.0	58.6	61.6	3.7	2.2	27.7	27.4	14.8	30.1

* Other includes Asian/Pacific Islander, Native American, Unknown and Other races
** Age and Vintage as of enrollee's study start date (1992-1994)
*** HCFA, BDMS, ESRD PMMIS - April, 1994 Update

Table 8: Social Characteristics of Demonstration Enrollees vs. ESRD Dialysis Population

	Demo Enrollees*	ESRD Pop'n**
MARITAL STATUS		
Married	35.21%	49.60%
Widowed	29.58%	18.40%
Separated	2.82%	4.80%
Divorced	14.08%	11.30%
Single	12.68%	15.90%
missing	5.63%	na
# HOUSEHOLD MEMBERS* **		
1	15.09%	7.76%
2	49.06%	52.39%
3	16.98%	20.28%
4 or more	18.87%	19.56%
EDUCATIONAL STATUS		
< high school grad	44.62%	45.40%
high school grad	27.69%	33.40%
some college	12.31%	12.30%
college grad	15.38%	9.00%

* Demo information based on beneficiary surveys (N=71)
** ESRD population based on Case Mix Adequacy Survey of dialysis patients(N=4223)
*** Based on n=53 and n=3323 for demo and ESRD pop. respectively

Note:Percentages and averages for each category are based on reported records.

renal failure (42 percent vs. 28 percent). Diabetes as the cause of renal failure is the highest risk factor for morbidity and mortality among ESRD patients.

Since the experiment was intended for those extremely sick patients who did not have someone to help them with dialysis, it is not surprising that the demonstration enrollees came from smaller households. Fewer participants were married, while more were divorced and a substantially higher percentage was widowed. Also, the percentage of people who reported living alone was greater among the demonstration sample.

3.2.3 Clinical Characteristics of Demonstration Enrollees Compared to ESRD Dialysis Population

Table 9 confirms the fact that demonstration enrollees were generally much sicker than the general ESRD dialysis population.

Arrhythmia, or irregular heart beat, is a very serious condition that predisposes patients to sudden death. Its rate is much higher in the population from the demonstration than for all ESRD dialysis patients (39 percent vs. 28 percent). The comorbidity factors that most generally indicate coronary or artery disease (CHD CAD) were only slightly elevated in the demonstration group (CHD, CAD, or CABG). However, the comorbidities indicating the most serious degree of CAD CHD are much more elevated. Myocardial infarction and cardiac arrest were both nearly double the general rate.

Problems of cerebrovascular disease (e.g., stroke) are also notable. Cerebrovascular accident, the more serious category of cerebrovascular disease, is sharply higher (33 percent vs. 13 percent) among demonstration enrollees. Even the rarer, milder form, i.e., transient ischemic attack, is also higher (4.5 percent vs. 3.1 percent). Another serious condition, poor blood circulation due to peripheral vascular disease including claudication, is almost twice as high in this population. Claudication is limping caused by lack of blood supply to the legs, a sign of peripheral vascular disease. This elevated rate is consistent with the ambulation problems characteristic of demonstration patients. Overall, the large excess in severe CHD, CAD, peripheral vascular disease, and cerebrovascular disease among demonstration patients indicates a consistent pattern of arteriosclerotic disease which is clearly associated with

elevated mortality risk (USRDS, 1992). Congestive heart failure is much more frequent in the demonstration enrollees, but not in its more severe form, i.e., pulmonary edema.

Cancer is also a risk factor, and neoplasms are elevated among demonstration enrollees. Worse, the severe cancer of known metastases, though infrequent in either population, is almost three times more common in the demonstration group. Chronic obstructive pulmonary disease is somewhat higher in the demonstration population, but not strikingly so. In its more serious form, requiring the prescription of home oxygen, there is little difference.

Hepatitis is lower among enrollees but it is rather rare and may have been poorly documented by the demonstration units' records sent to the networks for data abstraction; the only two reported instances were marked "suspected."

Other comorbidities (e.g., hypertension) either had little difference between the two groups or were of lesser clinical significance, or both. AIDS and HIV were not disclosed for most patients.

The severity of comorbid conditions is much more important than the number of conditions. The demonstration group has more conditions by total numerical count (just over four vs. three). More importantly, demonstration enrollees are higher in prevalence of truly serious conditions.

In addition to comorbid conditions, nutritional status gives an indication of a patient's well being. Undernourishment is also an indicator of high risk for ESRD patients. Table 9 presents several relevant measures. Serum albumen levels are lower for enrollees. Lower values indicate higher risk, and there is a steep gradient of mortality associated with lower levels. A risk-raising judgment of undernourishment for 30 percent of demonstration enrollees is much higher than the 17 percent general rate. By contrast, the rate of obesity was about a third lower in the demonstration group than in general. Finally, serum creatinine is another indicator of high mortality risk in dialysis patients. This outcome measure appears to relate more to the extent of a patient's muscle mass rather than to the level of kidney function. Demonstration patients had less muscle mass, again indicating poor nutrition. The two groups varied slightly in terms of percentage of well-nourished patients, which included the remaining patients in addition to those who had missing data and therefore were not reported. Other

clinical indicators listed at the bottom of Table 9 (e.g., Cholesterol Level) either had little difference between the two groups or were of lesser clinical significance, or both.

The presence of more comorbid conditions and poorer nutritional status indicates that the patients who enrolled in the demonstration were sicker than the average person with ESRD. This finding should not be surprising due to the patient criteria, and it probably lends some explanation to the high death rate of the demonstration enrollees.

3.2.4 Characteristics of Enrollees -- Survey Results

The survey of the demonstration enrollees yielded 71 responses. Thirty-eight of these surveys were conducted with the participant him/herself. Thirty-three were conducted with proxies for the beneficiary (e.g., family member, care-giver) because the beneficiary had expired or was incapable of responding directly. Responses from proxies were far less complete than those obtained directly from the beneficiaries. Many of the subjective questions (e.g., those that related to beneficiaries' attitudes about the care received) could only be asked of beneficiaries themselves.

As discussed above, the limited sample size prevented robust statistical analysis between the two groups. However, simple comparisons between the control and experimental groups and analysis of the survey sample as a whole are possible. Among the topics covered by the survey's range of questions were the following: beneficiary satisfaction with dialysis care (from home-aides and from centers) prior to the demonstration; issues related to traveling to the dialysis centers; self-reported measures of health; and nursing home status. Each of these topics is discussed below.

Beneficiary Satisfaction: Prior to enrolling in the demonstration, some patients dialyzed in-center and some dialyzed at home. Beneficiaries who had paid aides (from a source other than Medicare) during the 12 months prior to enrolling in the demonstration were asked how satisfied they had been with the level of care they received from paid aides. This question was not asked of proxy respondents. Of the 15 beneficiaries who answered this question, 13 (87 percent) responded they were very satisfied and 14 of the 15 (93 percent) responded they were very or somewhat satisfied. Beneficiaries who had received dialysis treatment from dialysis facilities in the 12 months prior to enrolling in the demonstration were

Table 9: Clinical Characteristics of Demonstration Enrollees vs. ESRD Dialysis Population

	Demo Enrollees*	ESRD Pop'n**
COMORBID CONDITIONS (% for each)		
Arrhythmia or Atrial Fibrillation	39.40%	27.50%
CHD or CAD or CABG	50.00%	45.60%
Myocardial Infraction	30.30%	14.70%
Cardiac Arrest	4.50%	2.50%
Cerebrovascular Accident	33.30%	12.80%
Transient Ischemic Attack	4.50%	3.10%
Peripheral Vascular Disease or Claudication	39.40%	21.60%
Congestive Heart Failure	69.70%	42.00%
Pulmonary Edema	18.20%	20.30%
Neoplasm	15.20%	9.50%
Known Metastases	4.50%	1.70%
Chronic Obstructive Pulmonary Disease, including Asthma	18.20%	13.20%
Home Oxygen Prescribed	1.50%	1.40%
Hepatitis	1.5%***	3.40%
History of Hypertension	84.80%	84.00%
Cirrhosis	0.00%	1.60%
Pericarditis	7.60%	6.20%
HIV status	na	0.70%
AIDS diagnosis	na	0.40%
NO. OF COMORBIDITIES (avg/person)	4.21	3.12
OTHER INDICATORS:		
Serum Albumin (Avg. g/dL)	3.37	3.69
Under-nourished/cachetic	30.30%	17.10%
Obese	12.10%	17.50%
Serum Creatinine (Avg. mg/dL)	7.39	11.11
Cardiomegaly by X-ray (% having)	50%	44.90%
Left Ventricular Hypertrophy (% having)	34.80%	39.00%
Cholesterol Level (Avg. mg/dL)	169.28	175.97
Serum Phosphorus (Avg. mg/dL)	5.38	5.96
Hematocrit Level (%)	28.79%	28.55%

* Demo information based on Medical Record Forms received (N=66)

** ESRD population based on Case Mix Adequacy Survey of dialysis patients (N=4223)

*** Suspected to have condition

asked how satisfied they had been with their treatment. The question was not asked of proxy respondents. Of the 24 beneficiaries who responded to this question, 13 (54 percent) said they were very satisfied with the care they received, and 21 of the 24 (88 percent) said they were very satisfied or somewhat satisfied. In general, the responses to this category of questions on the survey indicated a high degree of satisfaction with care received by the beneficiaries in both the home and facility settings.

Travel to Dialysis: Beneficiaries who previously dialyzed at dialysis facilities were asked about the mode of transportation by which they traveled to the facility. These questions were asked of proxy respondents, as well. When asked if the beneficiary traveled by ambulance, 20 said yes, 27 said no, one did not know, and 23 (mostly proxy respondents) did not respond to this item. Thus, 42 percent of those who responded to this question and 28 percent of the whole sample said they used an ambulance to travel to the dialysis facility. The most frequently acknowledged form of transportation was by a private vehicle or other free transportation; 39 percent of the whole sample (58 percent of those who responded) acknowledged using this form. Also frequently cited was the use of a van or ambulette service; 25 percent of the whole sample (38 percent of those who responded) cited this means. (Many respondents indicated they used multiple means of transportation.)

Of the 20 responding patients and proxies who said that ambulances were used for transportation to dialysis prior to the demonstration, 15 (75 percent) said the bill for this travel was paid fully or in part by Medicare. Ambulance travel to maintenance dialysis is a Medicare-covered service if there is medical necessity and if the destination is a hospital-based dialysis facility. It is possible that some of the ambulance use was to freestanding dialysis facilities, or that medical necessity was not certified and, in those cases, Medicare presumably did not pay. However, of the 27 respondents who reported that a taxi, limousine, van, or ambulette was used to travel to dialysis prior to the demonstration, 22 percent said Medicare paid something for this service. But transportation in these vehicles is not a Medicare-covered service. It seems likely that some respondents may have been confused about payment sources, possibly confusing Medicare from Medicaid, since the latter does pay for a substantial and varied amount of dialysis transportation.

Additional information acquired anecdotally throughout the demonstration suggested inadequacies in some of the transport systems may explain patients' interest in home aides. Common complaints were:

- The schedule of many health-related transport systems does not fit well with dialysis schedules. Dialysis facilities often dialyze people in 4-hour shifts and a patient arriving too late may not have sufficient time on the machine, or a patient anxious not to miss the ride will insist on terminating the session prematurely.

- Drivers in "curb to curb" transport systems, as well as dialysis staff, often will not assist patients into and out of the vehicles and up to the door, due to time constraints and/or concerns about insurance liability limitations. Some patients needing assistance must pay someone to ride with them three times a week to the dialysis facility, wait 3 or 4 hours, and ride with them on the return trip, for the sole purpose of providing assistance to and from the vehicles.

- Some "portal to portal" transport systems operate only within a city or county, and even wheelchair and stretcher patients may have to be unloaded at the boundary line and loaded onto another vehicle operating in the other geopolitical jurisdiction, three times a week, going to and from dialysis.

- Medicare carriers and intermediaries make coverage decisions that often differ from those made by their counterparts elsewhere in the U.S., not only in regard to what constitutes medical necessity for an ambulance to dialysis, but also in regard to whether a gurney, which would permit a stretcher patient to be transported to dialysis in the family van, is "durable medical equipment" and covered by Medicare.

- Wheelchair patients are often mishandled by transport system employees authorized to assist them, but poorly trained for the task. During the course of the demonstration, several incidents were recounted of (non-enrolled) wheelchair patients inadequately

secured in wheelchair vans and thrown onto the floor during the ride; in one case, the patient died as a result.

Health Measures: As was noted, the smallness of the sample prevents effective comparison between the treatment group and the control group. However, taken as a whole, the survey responses reveal a population with high morbidity. For example, of the 37 beneficiaries who responded to the question asking them how much bodily pain they had suffered during the last 4 weeks, 23 (62 percent) said they had suffered moderate, severe, or very severe pain. Other items relating to functional status corroborate this picture of medically and physically compromised patients, as would be expected given the demonstration's eligibility criteria.

Nursing Home Status: Of the 71 respondents, 16 (23 percent) reported that they (or the beneficiary for whom they responded) lived in a nursing home or institution. Residents of SNFs were excluded from the demonstration, so it is likely some of these 23 percent resided in other types of institutions (e.g., intermediate care facilities) or were admitted to SNFs later in the demonstration without notice being given of a formal withdrawal.

3.3 Outcomes

3.3.1 Withdrawal from the Demonstration

Of the 91 randomized patients, 14 withdrew from the demonstration; 10 experimentals before receiving services, and 4 controls. One unit withdrew all four of its patients when the random assignment only gave aides access to half its patients; in its view, the "wrong" ones. Withdrawals left 77 patients in the demonstration (41 control group patients and 36 experimental). Possibly, notices of formal withdrawals were more likely to be submitted for patients in the experimental group than for controls, since the reason for withdrawal usually interrupted the process of preparation for an aide. Usually, patients were withdrawn because they had become too ill for home dialysis, or had been admitted to a hospital or nursing home while the facility was in the process of obtaining an aide or getting a dialysis machine installed in the home. In one case, the home water supply could not be adequately conditioned for dialysis.

3.3.2 Home Aide Services

Only 20 of the 36 experimental patients who had not withdrawn from the demonstration received an aide. Among the 16 who did not, 12 died before the shift to home care could take place, and 4 were still alive and awaiting aides at the time data analysis began.

Facilities that provided home hemodialysis aides to enrollees in the experimental group were asked to provide information about the aide. This information was provided for 20 patients who received aide services. These 20 patients were served by 17 aides (2 aides served 2 patients each; 1 aide served 3 patients; 1 patient had 2 aides).

Only 10 of the 17 aides had any education, training, or credentials in health care. Two were certified in cardio-pulmonary resuscitation (CPR); three were LPNs; three were certified as dialysis technicians; one was certified as a nurse's assistant; and one was an RN. However, in years of experience with dialysis, aides ranged from 1 to 13, with the median being 6 1/2 years. Six had no previous experience as a home hemodialysis aide, and one had 8 years of experience; the median was 1 1/2 years of experience.

Half of the aides travel less than an hour going to and from the patient's home; half travel an hour or more. The range is from 20 minutes to 3 hours. In the absence of data, one hour of travel time had been factored into the rate-setting formula. This data suggest the factor was probably adequate.

3.3.3 Dialysis Outcomes

Table 10 shows various treatment factors dealing with hemodialysis. In contrast to the general ESRD population, the enrollees, possibly due to their poorer health, had a longer average hemodialysis session and more sessions per week. Recombinant human erythropoietin (EPO) is a drug to treat anemia of ESRD patients, and studies have shown it improves patients' quality of life (USRDS, 1994). The percent of demonstration patients receiving EPO was 88 percent, which is around 17 percentage points higher than for other ESRD patients. A marked difference between the two samples was in reuse of the dialyzer: 75 percent of the national sample had reuse compared to only 14 percent of the demonstration patients. For extremely sick ESRD patients, the dialyzer is often not reused, so the low reuse among the participants might reflect a more medically precarious population. This could also be a

TABLE 10: Treatment Characteristics of Demonstration Enrollees vs. ESRD Dialysis Population

	Demo Enrollees*	ESRD Pop'n**
EPO (%)	88.50%	71.30%
Acetate Bath (%)	12.90%	14.60%
Bicarbonate Bath (%)	87.10%	83.60%
Avg. hemo time (hrs)	3.35	3.25
avg. # of sessions/wk	3	2.92
reuse(%)	14.30%	75.40%

* Demo information based on Medical Record Forms received (N=66)
** ESRD population based on Case Mix Adequacy Survey of dialysis patients (N=4223)

facility-related factor, i.e., facilities participating in the demonstration may be less likely to reuse dialyzers than would dialysis facilities in general.

The medical record data collected by the ESRD networks in 6-month reports for each patient was analyzed to compare experimental patients with control patients in terms of clinical indicators that measure adequacy of care. There was at least one 6-month report for 16 (80 percent) of the 20 experimental patients who had aides, and for 28 (62 percent) of the 45 controls, but for only 5 (19 percent) of the 26 experimental patients who never received aides.

The total number of reports for each of these 3 groups showed a similar pattern: a total of 28 6-month reports for the 16 experimental patients who had aides (an average of 1.75 per patient); 48 reports for the 28 controls (an average of 1.71 per patient); and only 1 report each for the 5 experimentals who never received aides.

Values from five items of data were used from each of the 6-month reports, to measure the quality of care:

- Kt/V Urea (delivered) $=>1.0$ -- 1st quarter of the 6-month period
- Kt/V Urea (delivered) $=>1.0$ -- 2nd quarter of the 6-month period
- Pre-/post-dialysis BUN reduction $=>60\%$ -- 1st quarter of the 6-month period
- Pre-/post-dialysis BUN reduction $=>60\%$ -- 2nd quarter of the 6-month period
- Serum albumen $=>3.5$ gm/dl in at least two of the three months prior to the date of the medical record abstraction

Thus, there were 140 data points (5 items of data in each of 28 reports) for the experimental patients who had aides; 240 data points (5 items of data in each of 48 reports) for the controls; and 25 data points (5 items of data in each of 5 reports) for the experimental patients who never received aides. Data were actually available for 71 percent of the data points for experimentals who had aides; 68 percent of the data points for controls; and 84 percent of the data points for experimental patients who never received aides.

Scoring was binary at each data point, i.e., adequate or inadequate. For example, Kt/V was equal to or greater than one, which was considered to be adequate, or it was less than one, which was considered to be inadequate. This coding permitted an overall score to be calculated as the ratio of adequate outcomes to inadequate outcomes. In terms of this ratio, experimental patients who received aide services had 5.6 adequate outcomes for every one

inadequate; controls had 2.1 adequate outcomes for every one inadequate; and experimental patients who had not received aides had 2.0 adequate outcomes for every one inadequate.

There are three possible explanations for these differences: One explanation is that the observed differences across demonstration groups are an artifact created by the small numbers of patients in each group, and would not be observed with larger groups. A second explanation is the small group of patients who were randomly assigned to receive home aides and who actually used these aide services, differed in some unobserved but important respects from the other control and experimental patients. For example, the patients who used home dialysis aides may have been more stable and had fewer comorbidities than those who did not use home dialysis aides, making them better candidates for home dialysis and yielding better dialysis outcomes. The patients who survived to receive aides, in that they were not withdrawn from the demonstration and did not die before they could receive an aide, were probably healthier and might have had better outcomes than the others regardless of dialysis location or services. A third explanation is that dialyzing at home with a trained aide, rather than traveling to dialysis facilities, resulted in better dialysis outcomes.

3.3.4 Mortality

The overall death rate was high. During the 2 year and 9 month period studied, 78 percent of the enrollees died. However, although the numbers are too small for conclusions to be drawn, it is interesting to note there was a lower mortality rate among those patients who did receive aides. As of January 1, 1995 (8 months after the end of the enrollment period), 67 percent (14 out of 21) of the experimental patients who received aides had died, by contrast to 80 percent (12 out of 15) of the experimental patients who did not receive aides, and 83 percent (34 out of 41) of the controls.

As with the dialysis outcome data, the same three explanations for these mortality rates apply: Given the small number of patients, the observed mortality rates may be an artifact that would not be replicated with larger groups; the patients who used home aides may be a select subset of the entire demonstration population who might have had better survival rates regardless of dialysis location or services; or, possibly, home dialysis with an aide may reduce mortality.

3.3.5 Medicare Costs for Paid Home Hemodialysis Aides

HCFA's Office of Demonstration Support processed the claims for all home aide care under this demonstration. From these claims, costs per respondent can be ascertained. Note that these figures reflect both differences in unit costs across participants and differences in utilization.

Twenty-one participants in the demonstration were members of the experimental group and eventually received a home hemodialysis aide. Two grandfathered (former HIC) patients also received home aides as part of the program but were not members of the experimental group. Claims for services they received are included in these measures of the costs of services received from program-related home aides. Thus, there are 23 participants whose claims are included in these calculations.

The earliest claims from the demonstration are from April 1992, the date patients began enrolling in the program. The most recent processed claims are through the end of 1994. Over this period, total program claims equal $152,133. This amounts to an average expenditure per aide-recipient of $6,614 during this period.

The average claims charge per month of participation for the 23 enrollees is $573.[4] The average number of months with bills to HCFA is 10 per enrollee. As of January 1, 1995, of the original 23 individuals, 7 -- one of whom was a grandfathered (HIC) patient -- were still receiving home-aide care under the auspices of this program. Participants who received only 1 or 2 months of care had much lower average charges per month and per claim. Excluding those who received less than 3 months of services, the average charge per month was $643.

4 Number of months of participation is determined from the date of the first claim processed by HCFA through the date of the latest claim processed. This reflects when an individual actually began receiving care under the program and the individual's current status (i.e., presently receiving home aide services, no longer receiving these services, expired.)

4. CONCLUSIONS

The demonstration had too few enrollees to support statistical analysis, and the data can only be regarded as suggestive. However, the following conclusions can be tentatively drawn:

- The vast majority of patients in this demonstration were not distressed with their pre-demonstration dialysis arrangements -- 93 percent (14 out of 15) of those who had home hemodialysis aides paid by insurers other than Medicare, and 88 percent (21 out of 24) of those who had in-facility dialysis, responded they had been somewhat or very satisfied.

- The eligibility criteria that were Congressionally-mandated for this demonstration, in general, characterize patients who are too ill for home hemodialysis. Thus, a home hemodialysis aide is not likely to be an alternative for most patients for whom an ambulance is medically necessary.

- Ambulance transport to dialysis was physician-certified as medically necessary for every one of the patients in this demonstration. Yet the majority, including many of the sickest patients, were using other forms of transportation before the demonstration began (mostly private vehicles, ambulates, and vans). This was because the vast majority of enrollees were from independent, i.e., not hospital-based facilities, and Medicare does not pay for ambulance transport to independent facilities, which comprise the majority of dialysis facilities.

- The patients who were enrolled in the demonstration were somewhat older and much sicker than the ESRD population in general, with far more comorbid conditions documented in medical records. During the 2 year and 9 month period studied, 78 percent of the enrollees died. This is nearly twice the mortality rate than among the

general ESRD population, which had a 40 percent mortality rate over a comparable period.

- The rate-setting formula that was Congressionally-mandated yielded rates that were probably low, relative to the care requirements of many of these patients. The majority of the aides used in this demonstration had dialysis experience, but carried little in the way of health care credentials.

- Although the numbers are small and do not permit conclusions about quality of care, demonstration patients who dialyzed at home with the assistance of aides had better dialysis outcomes and a lower mortality rate than control and experimental patients who did not have demonstration aides for home dialysis.

4.1 Plans for Additional Analyses

A series of additional analyses have been added using larger data sets, including HCFA's information systems, to explore issues that interested the Congress but could not be addressed through the demonstration, given the small number of patients enrolled.

Abt Associates with The Urban Institute will perform case studies of ambulance and nursing home use. In order to gain insight into costly ambulance use among ESRD patients, heavy users will be identified (e.g., those who exceed a predetermined dollar or use limit, or specific percentage level for either usage or dollars). Interviews will be conducted with a number of dialysis providers serving this group of patients, to explore patterns and determine factors necessitating ambulance use, with a view to possible policy implications.

Another case study concerns residents of nursing homes. Evaluation staff will identify ESRD patients who reside in nursing homes, match them with their principal dialysis provider, and interview the dialysis and nursing home providers. The purpose is to understand whether dialysis services could be provided in nursing homes, what barriers exist, and whether this service location could reduce costly (and hazardous) ambulance trips for frail persons requiring thrice-weekly dialysis. In addition, staff will identify the intersection of the two populations

and will conduct statistical comparisons of these patients with the rest of the ESRD population.

Another study will identify unusually high-cost ESRD patients and determine through statistical regression what clinical conditions and demographic factors are associated.

A final analysis will be an in-depth clinical and managerial investigation of a few classes of extreme outliers to determine which health care cost components distinguish these highest cost ESRD patients from lower cost patients. Data on all procedures will be obtained on these extreme outliers and matched against comparison cases which will be reviewed by expert clinicians to consider possible explanations of differential expenses.

The results of these additional analyses are expected to provide HCFA and Congress with more information that may be useful in developing payment policy alternatives for the ESRD population.

REFERENCES

Paul Eggers, Health Care Financing Administration, personal communication, 1990.

General Accounting Office (GAO), *Payments for Home Dialysis Much Higher Under Reasonable Charge Method*, GAO/HRD-90-37, October, 1989.

Health Care Financing Administration (HCFA), Annual ESRD Facility Survey, 1994.

Urban Institute, unpublished data analyses for the Health Care Financing Administration's Survey of Dialysis Institutions (SODI) Study, 1985.

Urban Institute, "Implementation and Evaluation of the Staff-Assisted Home Dialysis Demonstration Project," technical proposal submitted to the Health Care Financing Administration, April 9, 1991.

U.S. Renal Data System (USRDS), 1992 Annual Data Report, the National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, August 1992, Chapter 4.

U.S. Renal Data System (USRDS), 1994 Annual Data Report, the National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, June 1994.

Appendix A -- Legislation Mandating Demonstration

"(II) for erythropoietin provided during a subsequent year, in an amount determined to be appropriate by the Secretary, except that such amount may not exceed the amount determined under this clause for the previous year increased by the percentage increase (if any) in the implicit price deflator for gross national product (as published by the Department of Commerce) for the second quarter of the preceding year over the implicit price deflator for the second quarter of the second preceding year."

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to erythropoietin furnished on or after January 1, 1991.

(d) SELF-ADMINISTERED ERYTHROPOIETIN.—

(1) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), is amended—

(A) by striking "and" at the end of subparagraph (O);

(B) by adding "and" at the end of subparagraph (P); and

(C) by adding at the end the following new subparagraph:

"(Q) erythropoietin for home dialysis patients competent to use such drug without medical or other supervision with respect to the administration of such drug, subject to methods and standards established by the Secretary by regulation for the safe and effective use of such drug, and items related to the administration of such drug;".

(2) COVERAGE FOR METHOD II PATIENTS.—Section 1881(b) (42 U.S.C. 1395rr(b)) is further amended—

(A) in paragraph (1)—

(B) by striking "and (B)" and inserting "(B), and

(C) by striking "equipment." and inserting "equipment, and (C) payments to a supplier of home dialysis supplies and equipment that is not a provider of services, a renal dialysis facility, or a physician for self-administered erythropoietin as described in section 1861(s)(2)(Q) if the Secretary finds that the patient receiving such drug from such a supplier can safely and effectively administer the drug (in accordance with the applicable methods and standards established by the Secretary pursuant to such section)."; and

(3) by adding at the end of paragraph (11), as amended by subsection (c), the following new subparagraph:

"(C) The amount payable to a supplier of home dialysis supplies and equipment that is not a provider of services, a renal dialysis facility, or a physician for erythropoietin shall be determined in the same manner as the amount payable to a renal dialysis facility for such item."

(3) EFFECTIVE DATE.—The amendments made by paragraphs (1) and (2) shall apply to items and services furnished on or after July 1, 1991.

SEC. 4202. STAFF-ASSISTED HOME DIALYSIS DEMONSTRATION PROJECT.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Not later than 9 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall establish and carry out a 3-year demonstration project to determine whether the services of a home dialysis

staff assistant providing services to a patient during hemodialysis treatment at the patient's home may be covered under the medicare program in a cost-effective manner that ensures patient safety.

(2) NUMBER OF PARTICIPANTS.—The total number of eligible patients receiving services under the demonstration project established under paragraph (1) may not exceed 800.

(b) PAYMENTS TO PARTICIPATING PROVIDERS AND FACILITIES.—

(1) SERVICES FOR WHICH PAYMENT MAY BE MADE.—

(A) IN GENERAL.—Under the demonstration project established under subsection (a), the Secretary shall make payments for 3 years under title XVIII of the Social Security Act to providers of services (other than a skilled nursing facility) or renal dialysis facilities for services of a home hemodialysis staff assistant provided to an individual described in subsection (c) during hemodialysis treatment at the individual's home in an amount determined under paragraph (2).

(B) SERVICES DESCRIBED.—For purposes of subparagraph (A), the term "services of a home hemodialysis staff assistant" means—

(i) technical assistance with the operation of a hemodialysis machine in the patient's home and with such patient's care during in-home hemodialysis; and

(ii) administration of medications within the patient's home to maintain the patency of the extra corporeal circuit.

(2) AMOUNT OF PAYMENT.—

(A) IN GENERAL.—Payment to a provider of services or renal dialysis facility participating in the demonstration project established under subsection (a) for the services described in paragraph (1) shall be prospectively determined by the Secretary, made on a per treatment basis, and shall be in an amount determined under subparagraph (B).

(B) DETERMINATION OF PAYMENT AMOUNT.—(i) The amount of payment made under subparagraph (A) shall be the product of—

(I) the rate determined under clause (ii) with respect to a provider of services or a renal dialysis facility; and

(II) the factor by which the labor portion of the composite rate determined under section 1881(b)(7) of the Social Security Act is adjusted for differences in area wage levels.

(ii) The rate determined under this clause, with respect to a provider of services or renal dialysis facility, shall be equal to the difference between—

(I) two-thirds of the labor portion of the composite rate applicable under section 1881(b)(7) of such Act to the provider or facility (as adjusted to reflect differences in area wage levels), and

(II) the product of the national median hourly wage for a home hemodialysis staff assistant and the national median time expended in the provision of home he-

modialysis staff assistant services (taking into account time expended in travel and predialysis patient care).

(iii) For purposes of clause (ii)(II)—

(I) the national median hourly wage for a home hemodialysis staff assistant and the national median average time expended for home hemodialysis staff assistant services shall be determined annually on the basis of the most recent data available, and

(II) the national median hourly wage for a home hemodialysis staff assistant shall be the sum of 65 percent of the national median hourly wage for a licensed practical nurse and 35 percent of the national median hourly wage for a registered nurse.

(C) PAYMENT AS ADD-ON TO COMPOSITE RATE.—The amount of payment determined under this paragraph shall be in addition to the amount of payment otherwise made to the provider of services or renal dialysis facility under section 1881(b) of such Act.

(c) INDIVIDUALS ELIGIBLE TO RECEIVE SERVICES UNDER PROJECT.—

(1) IN GENERAL.—An individual may receive services from a provider of services or renal dialysis facility participating in the demonstration project if—

(A) the individual is not a resident of a skilled nursing facility;

(B) the individual is an end stage renal disease patient entitled to benefits under title XVIII of the Social Security Act;

(C) the individual's physician certifies that the individual is confined to a bed or wheelchair and cannot transfer themselves from a bed to a chair;

(D) the individual has a serious medical condition (as specified by the Secretary) which would be exacerbated by travel to and from a dialysis facility;

(E) the individual is eligible for ambulance transportation to receive routine maintenance dialysis treatments, and, based on the individual's medical condition, there is reasonable expectation that such transportation will be used by the individual for a period of at least 6 consecutive months, such that the cost of ambulance transportation can reasonably be expected to meet or exceed the cost of home hemodialysis staff assistance as provided under subsection (b)(4); and

(F) no family member or other individual is available to provide such assistance to the individual.

(2) COVERAGE OF INDIVIDUALS CURRENTLY RECEIVING SERVICES.—Any individual who, on the date of the enactment of this Act, is receiving staff assistance under the experimental authority provided under section 1881(f)(2) of the Social Security Act shall be deemed to be an eligible individual for purposes of this subsection.

(3) CONTINUATION OF COVERAGE UPON TERMINATION OF PROJECT.—Notwithstanding any provision of title XVIII of the Social Security Act, any individual receiving services under the

demonstration project established under subsection (a) as of the date of the termination of the project shall continue to be eligible for home hemodialysis staff assistance after such date under such title on the same terms and conditions as applied under the demonstration project.

(d) QUALIFICATIONS FOR HOME HEMODIALYSIS STAFF ASSISTANTS.—For purposes of subsection (b), a home dialysis aide is qualified if the aide—

(1) meets minimum qualifications as specified by the Secretary; and

(2) meets any applicable qualifications as specified under the law of the State in which the home hemodialysis staff assistant is providing services.

(e) REPORTS.—

(1) INTERIM STATUS REPORT.—Not later than December 1, 1992, the Secretary shall submit to Congress a preliminary report on the status of the demonstration project established under subsection (a).

(2) FINAL REPORT.—Not later than December 31, 1995, the Secretary shall submit to Congress a final report evaluating the project, and shall include in such report recommendations regarding appropriate eligibility criteria and cost-control mechanisms for medicare coverage of the services of a home dialysis aide providing medical assistance to a patient during hemodialysis treatment at the patient's home.

(f) AUTHORIZATION OF APPROPRIATIONS.—The Secretary shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund (established under section 1841 of the Social Security Act) of not more than the following amounts to carry out the demonstration project established under subsection (a) (without regard to amounts appropriated in advance in appropriation Acts):

(1) For fiscal year 1991, $4,000,000.
(2) For fiscal year 1992, $4,000,000.
(3) For fiscal year 1993, $3,000,000.
(4) For fiscal year 1994, $2,000,000.
(5) For fiscal year 1995, $1,000,000.

SEC. 4203. EXTENSION OF SECONDARY PAYOR PROVISIONS.

(a) EXTENSION OF TRANSFER OF DATA.—

(1) Section 1862(b)(5)(C)(iii) (42 U.S.C. 1395y(b)(5)(C)(iii)) is amended by striking "September 30, 1991" and inserting "September 30, 1995".

(2) Section 6103(l)(12)(F) of the Internal Revenue Code of 1986 is amended—

(A) in clause (i), by striking "September 30, 1991" and inserting "September 30, 1995";

(B) in clause (ii)(I), by striking "1990" and inserting "1994"; and

(C) in clause (ii)(II), by striking "1991" and inserting "1995".

(b) EXTENSION OF APPLICATION TO DISABLED BENEFICIARIES.—Section 1862(b)(1)(B)(iii) (42 U.S.C. 1395y(b)(1)(B)(iii)) is amended by striking "January 1, 1992" and inserting "October 1, 1995".

(c) INDIVIDUALS WITH END STAGE RENAL DISEASE.—

Appendix B -- Telephone Survey and Medical Record Abstraction Forms

Implementation & Evaluation
of the
Staff-Assisted Home Dialysis Demonstration

INTAKE SURVEY

[ITEMS IN CAPITAL LETTERS ARE INSTRUCTIONS AND ARE NOT READ ALOUD].

{Items in Italics explain differences between hardcopy version of interview and what will appear on computer screen during interview.}

DATE OF INTERVIEW: _____ / _____ / _____
MONTH DAY YEAR

[ASK TO SPEAK WITH DESIGNATED RESPONDENT OR ACCEPTABLE PROXY. IF UNAVAILABLE, SCHEDULE CALLBACK.]

INTRODUCTION

Hello. I'm _____ from Abt Associates, a research company in Cambridge, Massachusetts. We are doing a study for the Medicare program on staff-assisted home dialysis. We are interviewing the people who applied to participate in this study to help determine whether Medicare should pay for the services of home dialysis aides. As part of the research, we need to interview both those who do and those who do not currently have a home dialysis aide. This survey is voluntary and will not affect your Medicare or any other benefits. The information you provide will be kept strictly confidential.

I'd like to start by finding out how you dialyzed in each of the last 12 months, from (MONTH) until now. I need to know whether you dialyzed in a facility or at home. If it was at home, was it with the help of an aide paid by Medicare, an aide paid by someone else, or by someone like a friend or relative who was not paid.

1. We'll start with this month and work back to (MONTH) of last year.

(How are you dialyzing this month/ How did you usually dialyze last month/the month before last)?	THIS MONTH 1 2 3 4 5 6 7 8 9 10 11 MONTH AGO *Once the interviewer enters the month of the interview, those numbers will appear as actual month names.*
At home with a Medicare-paid aide	1.....1..1..1..1..1..1..1..1..1..1..1
At home with an aide paid by someone else	2.....2..2..2..2..2..2..2..2..2..2..2
At home with an aide who is not paid	3.....3..3..3..3..3..3..3..3..3..3..3
At a dialysis facility	4 .....4..4..4..4..4..4..4..4..4..4..4
Discontinued hemodialysis	5.....5..5..5..5..5..5..5..5..5..5..5

Other (SPECIFY)_____

Computer will generate three most recent changes and Q:2 for each.

2. In (MONTH), why did you change from (METHOD) to (METHOD)?

[DO NOT READ LIST. CODE ALL THAT APPLY. PROBE FOR COMPLETE RESPONSE]

MOVED 1
HOSPITALIZED 2
DISSATISFIED WITH AIDE 3
DISSATISFIED WITH FACILITY 4
COULD NOT GET AN AIDE 5
PROBLEMS WITH INSURANCE COVERAGE 6
DOCTOR RECOMMENDED CHANGE 7
OTHER (SPECIFY)_____

Computer will generate Q. 3 if any month in Q. 1 was coded "4":

3. During the past 12 months, at how many different facilities did you dialyze? _____

Computer will generate the following question for each, if answer was greater than 1:

Why did you change facilities? [DO NOT READ LIST. CODE ALL THAT APPLY. PROBE COMPLETE RESPONSE].

MOVED 1
HOSPITALIZED 2
DISSATISFIED WITH FACILITY 3
PROBLEMS WITH INSURANCE COVERAGE 4
DOCTOR RECOMMENDED CHANGE 5
OTHER (SPECIFY)_____

Computer will generate Q.4 if any month in Q.1 was coded "1", "2" or "3":

4. During the past 12 months, how many different dialysis aides did you have?

_____

Computer will generate the following question for each, if answer was greater than 1.

Why did you change aides?

– [DO NOT READ LIST. CODE ALL THAT APPLY. PROBE FOR COMPLETE RESPONSE].

MOVED 1
HOSPITALIZED 2
DISSATISFIED WITH AIDE 3
COULD NOT GET AN AIDE 4
PROBLEMS WITH INSURANCE COVERAGE 5
DOCTOR RECOMMENDED CHANGE 6
OTHER (SPECIFY)_____

Computer will generate Q.5 if any month in Q.1 was coded "1" or "2". [READ]:

The next questions are about the paid aide or aides who helped with your dialysis at home during the past 12 months.

Computer will generate this statement if answer to Q.4 is greater than 1. [READ]:

If you had more than 1 paid aide, please answer in terms of your average or usual experience.

5. During the past 12 months, how satisfied have you been with the level of care as provided by paid home aides? Would you say...

Very satisfied 1
Somewhat satisfied, or 2
Not satisfied at all 3
DON'T KNOW 4

6. How dependable do you feel your paid home aides have been in keeping appointments with you at the scheduled time? Would you say...

Very dependable 1
Somewhat dependable, or 2
Not dependable at all 3
DON'T KNOW 4

7. During this time have you had any problems with...

	Y	N	DK
Arranging for a paid aide	1	2	3
Missed, shortened or delayed dialysis sessions	1	2	3
Incompetent or inexperienced paid aides	1	2	3
Unresponsive or insensitive paid aides	1	2	3
High turn-over among paid aides, or	1	2	3
Have you had any other problems with paid aides (SPECIFY)_____	1	2	3

8. Do you feel that your health has been harmed as a result of inadequate or undependable paid dialysis aides?

Yes 1
No 2
DON'T KNOW 3

9. In general, during the past 12 months, do you feel that your paid aides have provided the kind of help and services you needed?

Yes 1
No 2
DON'T KNOW 3

10. How did you pay for your aides during the past 12 months? [READ CATEGORIES. CHECK ALL THAT APPLY]

Paid entirely by you or your family 1
Paid partially by you or your family 2
Paid by Medicare, entirely or in part 3
Paid by Medicaid, entirely or in part 4
Paid by private insurance, entirely or in part 5
Some other payment was arranged 6
(SPECIFY)_____
DON'T KNOW/UNSURE 7

Computer will generate Q.11-17 if any month in Q.1 was coded "4". [READ]:

The next questions are about your dialysis experiences in a dialysis facility.

Computer will generate this statement if answer to Q.3 is greater than 1. [READ]:

If you dialyzed in more than one facility, please answer in terms of your average or usual experience.

11. During the past 12 months, how satisfied have you been with your dialysis treatment at the dialysis facility? Would you say...

Very satisfied 1
Somewhat satisfied, or 2
Not satisfied at all 3
DON'T KNOW 4

12. In general, do you feel that your dialysis facility has provided the kind of help and services you needed?

Yes 1
No 2
DON'T KNOW 3

13. In general, have you had to wait more than 30 minutes at the dialysis facility for your appointment?

Yes 1
No 2
DON'T KNOW 3

14. During the past 12 months, have you travelled to a dialysis facility...

	Y	N	DK
By ambulance	1	2	3
By a private vehicle or other free transportation	1	2	3
By a taxi or limousine service	1	2	3
By a van or ambulette service	1	2	3
By public transportation, or	1	2	3
By another form of transportation	1	2	3

Computer will generate Q.15 if answer to Q.14 was ambulance, taxi or limousine, van or ambulette service

15. How did you pay for your transportation to dialysis sessions? [READ CATEGORIES. CHECK ALL THAT APPLY]

Paid entirely by you or your family 1
Paid partially by you or your family 2
Paid by Medicare, entirely or in part 3
Paid by Medicaid, entirely or in part 4
Paid by private insurance, entirely or in part 5
Some other payment was arranged 6
(SPECIFY)_____
DON'T KNOW/UNSURE 7

16. Do you feel that any of the ways you travelled was harmful to your health?

Yes 1
No (SKIP TO Q.18) 2
DON'T KNOW (SKIP TO Q.18) 3

17. Which form of transportation do you feel was harmful to your health? [DO NOT READ CATEGORIES. CODE ALL THAT APPLY]

AMBULANCE 1
PRIVATE VEHICLE 2
TAXI OR LIMOUSINE SERVICE 3
VAN OR AMBULETTE 4
PUBLIC TRANSPORTATION, OR 5
ANOTHER FORM OF TRANSPORTATION (SPECIFY) 6

_____

18. During the past 12 months, have you had any problems with...

	Y	N	DK
Arranging for travel to the dialysis facility	1	2	3
Paying for travel to the dialysis facility	1	2	3
The amount of travel time needed for dialysis sessions	1	2	3
Missed, shortened or delayed dialysis sessions, or	1	2	3
Have you had any other problems (SPECIFY)	1	2	3

[ASK ALL RESPONDENTS ALL REMAINING QUESTIONS]

19. During past 12 months, how many times a week have you been dialyzing?

_____ times each week

20. During the past 12 months, how many hours has each dialysis session been lasting?

_____ hours per session

21. Why did you decide to enter the home dialysis aide demonstration? Was it because...

	Y	N	DK
No one was available to help you with home dialysis	1	2	3
You lacked adequate insurance coverage for home dialysis assistance	1	2	3
You were tired of travelling to the facility for dialysis	1	2	3
You were dissatisfied with transportation arrangements to the facility	1	2	3
You were dissatisfied with dialysis services at the facility	1	2	3
You were interested in more personalized care	1	2	3
You were dissatisfied with past home dialysis arrangements, or	1	2	3
Was there some other reason (SPECIFY) _____	1	2	3

The next set of questions is about your physical health.

22. Compared to 12 months ago -- that is, since (MONTH) of 1991 -- would you say your health status now is...

Much better 1
Somewhat better 2
The same 3
Somewhat worse, or 4
Much worse 5

23. Compared to 4 weeks ago -- that is, since (PRIOR MONTH) -- would you say your health status now is...

Much better 1
Somewhat better 2
The same 3
Somewhat worse, or 4
Much worse 5

24. During the past 4 weeks, have you cut down on the amount of daily activities you regularly perform as a result of your physical health...

A great deal 1
Somewhat 2
Slightly, or 3
Not at all 4

25. During the past 4 weeks has your bodily pain been...

Very severe 1
Severe 2
Moderate 3
Mild 4
Very mild, or 5
Have you had no bodily pain 6

26. During the past 4 weeks, has pain interfered with your regular daily activities...

A great deal 1
Somewhat 2
Slightly, or 3
Not at all 4

27. Are you presently...

An active smoker 1
An occasional smoker 2
A former smoker, or 3
You were never a smoker 4

28. This next set of questions is about how you feel and how things have been with you during the past 4 weeks. For each item, please let me know whether you feel this way all of the time, most of the time, some of the time, a little of the time, or none of the time. How much of the time have you

	ALL OF THE TIME	MOST OF THE TIME	SOME OF THE TIME	A LITTLE OF THE TIME	NONE OF THE TIME
felt full of pep? . .	1	2	3	4	5
been a very nervous person?	1	2	3	4	5
felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5
felt calm and peaceful?	1	2	3	4	5
had a lot of energy?	1	2	3	4	5
felt depressed? . . .	1	2	3	4	5
felt worn out? . . .	1	2	3	4	5
felt happy?	1	2	3	4	5
felt tired?	1	2	3	4	5

29. During the past 4 weeks have you cut down on the amount of daily activities you regularly perform as a result of any emotional problems...

A great deal 1
Somewhat 2
Slightly, or 3
Not at all 4

30. During the past 12 months, have your physical health or emotional problems interfered with your normal social activities with family members and friends...

A great deal 1
Somewhat 2
Slightly, or 3
Not at all 4

The next set of questions I will ask are about how much you are able to move about. Your answers will not affect your Medicare or demonstration services in any way. Your answers will not be shared with Medicare authorities.

31. How many hours out of each 24-hour day do you spend in bed?

_____ hours per day

32. How do you usually get from your bed to a wheelchair and back again? (READ CATEGORIES.)

With total help from another person 1
With some help from another person 2
By yourself with the use of helping devices, or 3
By yourself without the use of helping devices 4

33. How do you usually move around in your wheelchair? (READ CATEGORIES.)

With help from another person 1
By yourself with the use of a power source, such as a battery 2
By yourself completely, or 3
Do you not use a wheelchair 4

34. Which of the following best describes how you usually get dressed? (READ CATEGORIES.)

With total help from another person 1
With some help from another person 2
By yourself with the use of helping devices 3
By yourself without the use of helping devices, or 4
Do you not get dressed 5

35. Which of the following best describes how you get in and out of a shower or tub. (READ CATEGORIES.)

With total help from another person 1
With some help from another person 2
By yourself with the use of helping devices 3
By yourself without the use of helping devices, or 4
Do you only take sponge baths 5

36. How do you usually eat or drink? (READ CATEGORIES.)

With total help from another person 1
With some help from another person 2
By yourself with the use of helping devices, or 3
By yourself without the use of helping devices 4

37. I am going to read a list of the types of persons who may be available to help you with your personal care or housekeeping tasks. Please tell me whether each person I mention is available to help you on a regular basis. Then, if the person is available,

A. Does he or she help with your personal care, such as bathing, dressing or eating; and

B. Does he or she help with housekeeping activities, such as grocery shopping, house cleaning, laundry or cooking?

	Is (PERSON) available?		IF YES: Does he or she help with your personal care?		Does he or she help with your housekeeping?	
	Y	N	Y	N	Y	N
Your spouse	1	2	1	2	1	2
Your father or mother	1	2	1	2	1	2
Another relative within your household	1	2	1	2	1	2
A non-relative within your household	1	2	1	2	1	2
A friend or relative not in your household	1	2	1	2	1	2
A nurse or home aide from a community agency .	1	2	1	2	1	2
A homemaker or chore worker from a community agency .	1	2	1	2	1	2
Some other person (SPECIFY) _____ _____ .	1	2	1	2	1	2

38. How many hours each day do you spend outside of your home for non-medical purposes?

_____ hours each day

Finally, I have a few background questions.

39. Do you currently live in...

An apartment or house 1
A nursing home or institution (SKIP TO Q.41) 2
A shelter, or (SKIP TO Q.41) 3
Do you live in some other place . . . . . .
(SPECIFY)_____ 4

40. Including yourself, how many persons live in your household?

1 1
2 2
3 3
4 or more 4

41. Are you presently...

Married and living with your spouse 1
Separated 2
Divorced 3
Widowed, or 4
Were you never married 5

42. Are you....

Black/African American 1
White 2
American Indian or Native Alaskan, or (SKIP TO Q.44) 3
Asian or Pacific Islander (SKIP TO Q.44) 4

43. Are you Hispanic?

Yes 1
No 2

44. Which of the following best describes the highest level of education you reached? (READ CATEGORIES)

Had some high school, but did not complete 1
Completed high school 2
Had some college, but did not complete 3
Completed college, or 4
Began or completed graduate school 5

45. Just before you began chronic maintenance dialysis, were you...

Employed full time, 30 or more hours per week 1
Employed part time, less than 30 hours per week 2
Temporarily laid off 3
Retired (SKIP TO Q.47) 4
Disabled (SKIP TO Q.47) 5
Unemployed (SKIP TO Q.47) 6
A student (SKIP TO Q.47) 7
A homemaker, or (SKIP TO Q.47) 8
Were you in some other work category (SPECIFY) 9

_____

46. Was your job...

Professional 1
Trade or sales related 2
Manual labor 3
Clerical, or 4
Was your job in some other category (SPECIFY) 5

_____

47. In addition to Medicare, do you currently have any other health insurance, such as...

	Y	N	DK
Medicaid	1	2	3
Private insurance	1	2	3
CHAMPUS, CHAMPVA, or military health care, or .	1	2	3
Do you have some other kind of health insurance (SPECIFY)_____ .	1	2	3

_____

That is the end of the survey; thank you for your cooperation.

unable to determine, and leave item (right) blank.

Medical Records Form

CONFIDENTIAL

STUDY START DATE

A. PATIENT AND FACILITY IDENTIFICATION

1. Network

2. Abstractor

3. Date this Form Completed

4. Patient's ESRD

5. Medicare Claim No.

6. Medicare Provider Number

7. Date of Birth

B. PATIENT HISTORY PRIOR TO STUDY START DATE (Please see top right box and instructions.)

8. Date of First Chronic Maintenance Dialysis, Regardless of Setting

9. Insurance Status in Addition to Medicare at Start of Study

1-Yes 2-No

a. Blue Cross

b. Medicaid

c. Private

d. VA

e. Other

f. None

10. Primary Cause of Renal Failure

1-Diabetes

2-Hypertension

3-Glomerulonephritis

4-Cystic Kidney

5-Other Urologic

6-Other Cause

7- Cause Unknown

SAMPLE

C. PATIENT HISTORY OF COMORBID CONDITIONS WITHIN 3 YEARS PRIOR TO STUDY START DATE (Please see top right box and instructions.)

11. Coronary Heart Disease (CHD) or Coronary Artery Disease (CAD)

1-Yes 2-No 3-Suspected

a. Prior Diagnosis of CHD/CAD or Angina

For b, c & d only: 1-Yes 2-No

b. Myocardial Infarction (MI)

c. Bypass Surgery (CABG), Coronary Angioplasty (PTCA), or Coronary Angiography

d. Cardiac Arrest within Past 5 Years

12. Cerebrovascular Disease

1-Yes 2-No 3-Suspected

a. Diagnosis of Cerebrovascular Accident (CVA, Stroke)

(If item 12a is "Yes," item num 12b blank.)

b. Any Transient Ischemic Attacks (TIA)

13. History of Peripheral Vascular Disease (PVD, PVOD)

For a & b only: 1-Yes 2-No 3-Suspected

a. Prior Diagnosis of PVD, PVOD

b. Amputation Due to PVD, PVOD

For c, d & e only: 1-Yes 2-No

c. Absent Foot Pulses

d. Claudication

e. Arteriography (Angiography) of Lower Extremities

14. Heart Disease

1-Yes 2-No 3-Suspected

a. Congestive Heart Failure

b. Pulmonary Edema

c. Pericarditis

d. Arrhythmia or Atrial Fibrillation

15. History of Hypertension

1-Yes 2-No 3-Suspected

(If item 15 is "No," skip to item 16.)

a. Duration (Years, Rounded) or Years Since Diagnosis

For b only: 1-Yes 2-No

b. Treated at Start of Study

16. Diagnosis of Diabetes

1-Yes 2-No 3-Suspected

(If item 16 is "No," skip to item 17.)

a. Duration (Years, Rounded) or Years Since Diagnosis

For b, ii and iii only: 1-Yes 2-No

b. Treated at Start of Study

(If item 16b is "No," skip to item 17.)

i. Dietary Treatment

ii. Medications

17. Lung Disease

1-Yes 2-No 3-Suspected

a. Chronic Obstructive Pulmonary Disease (COPD), Including Asthma

b. Home Oxygen Prescribed

18. Neoplasm, Excluding Skin Cancer

1-Yes 2-No 3-Suspected

(If item 18 is "No," skip to item 19.)

a. Neoplasm within Past 5 Years

b. Neoplasm 6 or More Years Ago

For c only: 1-Yes 2-No

c. Known Metastases

19. Liver Disease

1-Yes 2-No 3-Suspected

a. Hepatitis

b. Cirrhosis

20. HIV Status

1-Positive 2-Negative 3-Unknown 4-Cannot Disclose

21. AIDS Diagnosis

1-Positive 2-Negative 3-Unknown 4-Cannot Disclose

ABSTRACTOR:

Use space on Page 2 to cover any comments or explanations as a particular item.

box to left of item if unable to determine, and leave item (right) blank.

Staff-Assisted Home Dialysis Demonstration

Medical Records Form

CONFIDENTIAL

STUDY START DATE: mo / da / yr

D. CLINICAL MEASURES AT STUDY START DATE (Please see top right box and instructions.)

Items 22 - 38: Report Measures Documented Immediately Prior to Study Start Date, Unless Otherwise Specified. (Per instructions.)

22. Height at Any Time

ft. in. Or cm.

23. Largest Weight Gain During Last Week Prior to Study Start Date

(Post-dialysis to Pre-dialysis.)

lb. Or kg.

24. Nutritional Status Recorded in the Records

1-Obese/Overweight 2-Under-Nourished/Cachexia 3-Well Nourished

25. Change in Dry Weight During 3 Months Prior to Study Start Date

(Compare average of 3 consecutive post dialysis values near study start date and 3 months earlier.)

1-Weight Gain (10+ lbs. or 4.5+ kg.) 3-Change less than 10 lbs. or 4.5 kg.

2-Weight Loss (10+ lbs. or 4.5+ kg.)

26. Blood Pressure

(Average of 3 most recent consecutive values.)

a. At Start of Study, Pre-Dialysis

SBP / DBP

b. At Start of Study, Post-Dialysis

SBP / DBP

27. Hemodialysis

a. Usual Hours per Treatment

hr. : min.

b. Usual Number of Dialysis Sessions per Week

c. Number of Dialysis Sessions Missed in 4 Weeks Prior to Study Start Date

(In-hospital dialysis is not a "missed" session.)

For d code: 1-Yes 2-No

d. Reuse of Dialyzer in this Patient

e. Blood Flow Rate (BFR):

(If BFR varies, enter most common rate or prescribed rate.)

ml/min.

f. Dialyzer Type (See codes on Page 3.)

If code 700, please specify __________

For g code 1-Bicarbonate Bath 2-Acetate Bath

g. Dialysate Used or Prescribed

h. Vascular Access in Use

(Please specify primary and secondary.)

Primary Secondary

1-Fistula (Arterio-Venous Shunt) 2-Gortex Graft 3-Bovine Graft

4-Permanent Subclavian Catheter 6-Other 7-No Secondary Access

28. BUN & Weight Within 2 Weeks Prior to or After Study Start Date

(1st pre-dialysis measure and post-dialysis measure must be from the same date. 2nd pre-dialysis measure must be from exactly 2 days after the stated date, otherwise do not record 2nd measure.)

DATE: mo / da / yr

BUN: Pre Post Pre

WEIGHT: Pre Post Pre

Units (check one): lbs. kgs.

For items 29 & 30 report average of last 2 readings during 3 months prior to study start date or most recent reading if 2 are not available.

29. Serum Creatinine . mg/dl.

30. Serum Albumin . gm/dl.

For items 31 & 32 report data up to 1 year prior to 1 month after study start date.

31. Cardiomegaly by X-Ray

1-Yes 2-No

SAMPLE

32. Left Ventricular Hypertrophy

1-Yes 2-No

a. By EKG

b. By Echocardiography

For items 33, 34 & 35 report data during 3 months prior to study start date.

33. Bilirubin Total . mg/dl.

34. HBsAg

1-Positive 2-Negative

35. Lipids

a. Cholesterol Total mg/dl.

b. Triglycerides (If 1000+, code 999.)

mg/dl.

For items 36 & 37 report data during 1 month prior to study start date.

36. Serum Phosphorus . mg/dl.

37. Hematocrit (Rounded. If transfused give value before transfusion.) %

For a code 1-Yes 2-No

a. Transfused Patient

38. EPO Use

1-Yes 2-No

(If Item 38 is "Yes," report most recent weekly dosage.)

Note: not per dialysis dosage but per-week dosage.

, total units/week

ABSTRACTOR:

Staff-Assisted Home Dialysis Demonstration
Medical Records Form

STUDY START DATE: [ ][ ] [ ][ ] [ ][ ]

ABSTRACTOR:

Use this space to enter any comments or explanations to a particular item.

SAMPLE

DIALYZER TYPES BY MANUFACTURER OR PRODUCER

CODE	DIALYZER TYPE
	ASAHI
400	AM 100L
401	AM 150H
402	AM 150L
403	AM 150M
404	AM 200H
405	AM 200L
406	AM 200M
407	AM 200H
408	AM 200L
409	AM300M
410	AM 350M
411	AM-SD 40M
412	AM-SD 50H
413	AM-SD 50M
414	AM-SD 65H
415	AM-SD 65L
416	AM-SD 75H
417	PAN 50
418	PAN 150
419	PAN 200
420	PAN 250
	BAXTER
430	CF 12
431	CF 12-11
432	CF 12-11L
433	CF 15
434	CF 15-11
435	CF 23
436	CF 23-08
437	CF 25
438	CA 50
439	CA 70
440	CA 90
441	CA 110
442	CA 150
443	CA 170
444	CA 210
445	CT 110
446	CT 190
447	HT 80
448	HT 100
449	HT 130
450	HT 170
451	ST 12
	CD MEDICAL
460	3500
461	3500 HP
462	4000
463	4000 HP
464	4000 Low UFR
465	4000 Med UFR
466	4000 UHP
467	4000 ULTRA
468	CA 4500
469	CA 5000
470	CA 5100
471	CA 5200
472	CA 6000
473	SCE 70
474	SCE 90
475	SCE 135
476	SCE 155
477	DUO-FLUX
478	ULTREX 880
	CORDIS DOW (See CD MEDICAL)
	CDAK-Cons[illegible]
480	100 HG
481	200
482	200 HG
483	300
484	300 HG
485	400
486	400 HG
487	500 HG
488	HF 120
489	HF 140
490	HF 160
491	PPD 1.3
492	PPD 1.6
493	HF 70
494	HF 100
	ERIKA
	ENKA
500	APF 1
501	APF 2
502	APF 3
503	PCS A-10
504	PCS B-10
505	PCS C-10
506	FOCUS 70
507	FOCUS 70H
508	FOCUS 90
509	FOCUS 90H
510	FOCUS 120
511	FOCUS 120H
512	FOCUS 160
513	FOCUS 160H
	FRESENIUS
520	F4
521	F5
522	F6
523	F7
524	F8
525	F40
526	F50
527	F60
528	F80
	GAMBRO
530	Mini Minor
531	GF 80H
532	GF 80M
533	GF 120H
534	GF 120L
535	GF 120M
536	GF 180H
537	GF 180M
538	CFE 9
539	CFE 11
540	CFE 12
541	CFE 15
542	CFE 18
543	LUNDIA LC. -1H
544	LUNDIA LC. -1N
545	LUNDIA LC. -1L
546	LUNDIA LC. -2L
547	LUNDIA LC. -2N
548	LUNDIA LC. -3H
549	LUNDIA LC. -3L
550	LUNDIA LC. -3N
551	LUNDIA LC. -4H
552	LUNDIA LC. -4N
553	LUNDIA LC. -5H
554	LUNDIA LC. -5L
555	LUNDIA LC. -5N
556	LUNDIA LC. -6H
557	LUNDIA LC. -6N
558	LUNDIA LC.5 HIGH FLUX
559	LUNDIA LC.6 HIGH FLUX
560	LUNDIA PRO 3
561	LUNDIA PRO 5
	HOSPAL
570	BIOSPAL 1200S
571	BIOSPAL 1800S
572	BIOSPAL 2400S
573	BIOSPAL 3000S
574	DISSCAP 080E
575	DISSCAP 110E
576	DISSCAP 140E
577	DISSCAP 160E
578	FILTRAL-8
579	FILTRAL-10
580	FILTRAL-12
581	FILTRAL-16
582	FILTRAL-20
583	H-12-10
	NMC (See ERIKA)
	ORGANON-TEKNIKA
590	NEPHROS-ALLEGRO
591	NEPHROS-ANDANTE
592	NEPHROS-LENTO
593	NEPHROS-MODERATO
594	NEPHROS-PRESTO
	TERUMO
600	TAF 06
601	TAF 08
602	TAF 08M
603	TAF 10
604	TAF 10M
605	TAF 12
606	TAF 12M
607	TAF 15M
608	TAF 175
609	ICL-C061L
610	ICL-C081L
611	ICL-C101L
612	ICL-C121L
613	ICL-M081L
614	ICL-M101L
615	ICL-M121L
616	ICL-M151L
617	ICL-T150L
618	ICL-T175L
619	ICL-T220L
	TORAY
620	B1-1.3H
621	B1-1.6H
622	B1-2.1H
623	BK-1.0V
624	BK-1.6V
625	BK-2.1V
626	FILTRYZER B2-0.5
627	FILTRYZER B2-1.0
628	FILTRYZER B2-1.0H
629	FILTRYZER B2-1.2H
630	FILTRYZER B2-1.5H
631	FILTRYZER B1-2.1
	TRAVENOL (See BAXTER)
700	OTHER *(Please specify type on Page 2 of form.)*

Appendix C -- Original Solicitation Sent to Dialysis Facilities

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

6325 Security Boulevard
Baltimore, MD 21207

January , 1992

Dear Sir or Madam:

The Health Care Financing Administration (HCFA) will soon begin a Congressionally-mandated demonstration in which Medicare payment for home hemodialysis aides will be provided for a group of End Stage Renal Disease (ESRD) patients meeting specific eligibility criteria. Facility participation is important to the success of this demonstration. I am writing to you to explain the Demonstration and to ask you to let us know by January 24, 1992 whether your facility would be interested in participating and has potentially eligible patients.

Information regarding the demonstration is provided in the Enclosures:

Enclosure 1 is a Summary Fact Sheet which provides brief answers to questions you may have.

Enclosure 2 lists the rates of payment for home hemodialysis aides, sequenced by MSA code number. Your facility is in MSA number _____.

Dialysis facilities providing home hemodialysis aides under the demonstration will receive a special payment for each home hemodialysis session, in addition to the composite rate. This payment can be received and the service provided for the life of the patient, even after the 3-year demonstration ends, since Congress stipulated that patients receiving the service experimentally remain entitled to it, as long as they continue to meet the original eligibility criteria.

The Congressional mandate specifies that a few patients currently receiving special services arranged by HCFA automatically qualify for this demonstration. Our records indicate that you are currently serving one of these patients [insert patient name]. WHEN THE DEMONSTRATION BEGINS, YOUR CURRENT PAYMENT FOR THIS PATIENT'S HOME AIDE SERVICES WILL BE DISCONTINUED. You will receive the demonstration payment for continuing to provide home aide services to this patient.

Enclosure 3 is a Facility Interest Form for you to complete and return in the enclosed envelope, indicating whether or not you are interested in participating in the demonstration.

Please review the enclosed materials carefully. You may choose to participate whether or not you currently serve patients meeting the eligibility criteria.

We urge you to consider participating in the demonstration, so that we may obtain adequate information about a potential new benefit, and to help your patients who may qualify to receive this service. If you have patients you believe may be eligible for the demonstration, please indicate this on the Facility Interest Form in Enclosure 3 and return this form in the enclosed self-addressed envelope ***NO LATER THAN JANUARY 24, 1992.***

Even if you choose not to participate, please tell us why by returning the Facility Interest form in the enclosed envelope; it would be most helpful if you explain your reasons.

If you have questions about any aspect of the demonstration, please contact the Project Manager, Andrea Hassol, Abt Associates, Inc., 55 Wheeler St., Cambridge, Massachusetts 02138, telephone (617) 492-7100, between the hours of 9:00 and 5:00, Eastern Standard Time.

Thank you very much for your consideration and attention. Your cooperation is important to the success of this demonstration.

Sincerely,

Mary S. Kenesson
Director
Office of Demonstrations and Evaluations
Office of Research and Demonstrations

SUMMARY FACT SHEET

What are the goals of the Demonstration?

The purpose of the demonstration is to determine whether the services of a home hemodialysis staff assistant may be covered under the Medicare program in a cost-effective manner that assures patient safety.

What is the authority for the demonstration?

The demonstration was mandated in Public Law 101-508, enacted by Congress on November 5, 1990. The legislation mandates an interim report to Congress on December 1, 1992 and a final report to Congress on December 31, 1995.

What is the payment for home aide services?

Congress specified the rate-setting formula for home aide services. To find the rate you will receive for each home hemodialysis session provided by an aide, look under your MSA code number in Enclosure 2. The rate listed in enclosure 2 for your MSA is the amount you will receive for each hemodialysis session, *in addition to the composite rate.*

The rate includes 1 hour of average travel time (round-trip) for each home visit, and will be updated annually during the 3-year Demonstration.

The rate for home aides is an add-on to the composite rate. All other services you normally provide to dialysis patients are included in the composite rate. Providers offering home hemodialysis aides under the demonstration must operate under Method I reimbursement principles in section 2712 of the Provider Reimbursement Manual. That is, you may not bill separately for the purchase, delivery, installation, maintenance, repair, or testing of home hemodialysis equipment or supplies, nor for routine ESRD-related laboratory tests.

HCFA will pay on the basis of allowable charges. This means that HCFA will pay 80 percent of the rate listed for your MSA; the patient and any other payors will be responsible for the other 20 percent.

What are the patient eligibility criteria?

Congress stipulated that patients must be Medicare beneficiaries who: do not reside in a skilled nursing facility; are confined to bed or wheelchair; have a medical condition exacerbated by travel; are eligible for ambulance transportation to routine dialysis; and do not have a family member available to serve as hemodialysis aide.

Here is a clarification of those criteria:

"Skilled nursing facility" rules out skilled nursing facilities, but patients residing in intermediate care facilities or other group settings may be eligible. You should confirm that the living situation does not preclude the installation of a hemodialysis machine before you make the referral.

We will be sending you an application packet to complete for each patient. The application packet will include check-offs for a physician to state that the patient: is confined to bed or wheelchair; has a medical condition exacerbated by travel; and has a condition, which is expected to continue for at least 6 months, that makes it medically necessary for an ambulance to transport the patient to routine dialysis.

As you may know, outside of the demonstration, Medicare has two coverage criteria that must be met for patients to receive ambulance services for maintenance dialysis: it must be medically necessary for the patient to be transported by ambulance, and the destination must be a hospital-based dialysis facility. For purposes of demonstration eligibility, however, the destination requirement will not apply, so that both hospital-based and independent dialysis facilities can participate in the demonstration. The physician's statement in the application packet will be considered sufficient for the medical necessity requirement and the expected 6 months' duration.

The application packet we send you will also include a check-off for the patient to state that he/she has no family member available to serve as hemodialysis aide.

Can I refer a patient who meets the eligibility criteria but who is currently receiving home aide services paid for by a payor other than Medicare, or paid out of pocket?

Yes, if patients meet the eligibility criteria, they can participate in the demonstration even if they were receiving home aide services before the demonstration began.

What should I do if I have patients who may be eligible and I want to participate?

Complete the Facility Interest Form (Enclosure 3) and return it in the enclosed self-addressed envelope **BY JANUARY 24, 1992.** We will then send you an application packet. Complete the application materials for each patient who may be eligible and send these to your local ESRD Network. The Network will assure that the application is complete and will send it to HCFA's Office of Demonstrations and Evaluations where eligibility will be determined. If you have an eligible patient, you will be so informed and will be asked to send some information from the patient's medical record to your local ESRD Network.

What if I don't presently have eligible patients?

Whether or not you have eligible patients, and whether or not you choose to participate, we would appreciate your completing the Facility Interest Form and returning it in the enclosed envelope by January 24, 1992. If you do not have eligible patients at present, but would like to participate if one of your patients becomes eligible, you should indicate this on the form.

What happens if I have eligible patients? When can I receive payment for the home aide?

The Demonstration is designed as a clinical trial; this means that HCFA intends to randomize eligible patients into experimental and control groups. Experimental patients will receive home hemodialysis aides paid under the demonstration. Control patients will continue to receive their current dialysis services. This randomization is expected to occur in early May.

HCFA will send you a letter informing you about your patients' status as experimentals and controls. If you have eligible patients, you will also receive more information about the details of demonstration design and implementation and a Provider Agreement. Once that Provider Agreement has been signed and returned to HCFA, you can receive payment for the home hemodialysis aide. We expect that the Provider Agreement can be signed, and services begun, during May, 1992.

What qualifications are required for the home aide? Must he/she have previous home hemodialysis experience? Can I subcontract?

This is left to your judgment, since you will be responsible for both patient and aide, as you would be for in-facility hemodialysis. The legislation stipulates that the home hemodialysis aide must be qualified to perform this service.

The Congressional mandate for the demonstration specifies that aides must be able to provide patient care and technical assistance with the operation of a hemodialysis machine in the patient's home, and be able to administer medications to maintain the patency of the extracorporeal circuit. You must meet State regulations and comply with any requirements in State Nurse Practice Acts, in regard to the qualifications of home aides.

Even if you choose to provide the home aide services through a subcontractual arrangement, you will remain responsible for those services. You must also assure that the subcontractor, the patient, and your own facility, are all within reasonable proximity of each other, unless the patient resides in a very remote geographic area. For example, if your facility is in a major city, you cannot subcontract to provide home services to patients residing in another major city more than 100 miles away.

All persons providing home aide services, whether it is your own staff person or that of a subcontractor, must have training in home hemodialysis. Even personnel experienced with

in-facility dialysis should receive some training for home hemodialysis, and HCFA will pay for this training under the demonstration, if the aide has not previously been trained for home hemodialysis.

What is the payment for training home aides?

You will receive a one-time payment of $200 to cover home hemodialysis training for the aide and patient. In addition, the facility providing this training (your own or some other facility with which you have a training arrangement or agreement) will receive the usual $20.00 per training session to cover the cost of the trainer. This is the same amount that is currently paid to cover training costs for unpaid home aides.

What data are to be collected and who's doing the research?

HCFA has selected Abt Associates, Inc., a research and survey firm, as prime contractor for the evaluation. Under subcontract, the Urban Institute's Renal Program will collaborate in this project. Data will come from patient interviews, case-study interviews with facilities, and the HCFA data system. Also, ESRD Networks are under contract to HCFA to provide clinical data on both experimental and control patients every 6 months during the 3-year demonstration.

ENCLOSURE 2

DEMONSTRATION RATES OF PAYMENT FOR HOME HEMODIALYSIS AIDS, PER DIALYSIS SESSION

MSA Name	Area Wage Index	Payment Rate for Hospital-Based Facilities	Independent Facilities
ABILENE	0.9001	$45.05	$43.06
AGUADILLA	0.9000	$45.05	$43.06
AKRON	1.1030	$55.21	$52.77
ALBANY	0.9000	$45.05	$43.06
ALBANY-SCHENECTADY-TROY	0.9484	$47.48	$45.38
ALBUQUERQUE	1.0659	$53.35	$50.99
ALEXANDRIA	0.9439	$47.24	$45.16
ALLENTOWN-BETHLEHEM	1.0485	$52.48	$50.16
ALTOONA	1.0287	$51.49	$49.21
AMARILLO	0.9507	$47.58	$45.48
ANAHEIM-SANTA ANA	1.2758	$63.85	$61.03
ANCHORAGE	1.2886	$64.49	$61.65
ANDERSON (IN)	0.9863	$49.36	$47.18
ANDERSON (SC)	0.9000	$45.05	$43.06
ANN ARBOR	1.2773	$63.93	$61.11
ANNISTON	0.9000	$45.05	$43.06
APPLETON-OSHKOSH-NEENAH	1.0038	$50.24	$48.02
ARECIBO	0.9000	$45.05	$43.06
ASHEVILLE	0.9620	$48.15	$46.02
ATHENS	0.9000	$45.05	$43.06
ATLANTA	0.9516	$47.63	$45.52
ATLANTIC CITY	1.0477	$52.44	$50.12
AUGUSTA	0.9518	$47.64	$45.53
AURORA-ELGIN	1.1614	$58.13	$55.56
AUSTIN	1.0566	$52.88	$50.55
BAKERSFIELD	1.1911	$59.61	$56.98
BALTIMORE	1.1271	$56.41	$53.92
BANGOR	0.9367	$46.88	$44.81
BATON ROUGE	0.9874	$49.42	$47.24
BATTLE CREEK	1.0340	$51.75	$49.47
BEAUMONT-PORT ARTHUR	0.9677	$48.43	$46.29
BEAVER COUNTY	1.1264	$56.38	$53.89
BELLINGHAM	1.0097	$50.54	$48.30
BENTON HARBOR	0.9000	$45.05	$43.06
BERGEN-PASSAIC	1.2031	$60.22	$57.56
BILLINGS	0.9948	$49.79	$47.59
BILOXI-GULFPORT	0.9000	$45.05	$43.06
BINGHAMTON	0.9501	$47.55	$45.45
BIRMINGHAM	0.9879	$49.44	$47.26
BISMARCK	0.9635	$48.22	$46.09
BLOOMINGTON	0.9456	$47.33	$45.24
BLOOMINGTON-NORMAL	0.9438	$47.24	$45.15
BOISE CITY	1.0585	$52.98	$50.64
BOSTON-SALEM-BROCKTON	1.1456	$57.34	$54.81
BOULDER-LONGMONT	1.1702	$58.57	$55.98
BRADENTON	0.9250	$46.30	$44.25
BRAZORIA	1.0333	$51.72	$49.43
BREMERTON	0.9325	$46.67	$44.61
BRIDGEPORT-NORWALK-DANBURY	1.2081	$60.46	$57.84
BROWNSVILLE-HARLINGEN	0.9458	$47.34	$45.25
BRYAN-COLLEGE STATION	0.9228	$46.19	$44.15
BUFFALO	1.0238	$51.24	$48.98
BURLINGTON (NC)	0.9000	$45.05	$43.06
BURLINGTON (VT)	0.9785	$48.97	$46.81

MSA Code	MSA Name	Area Wage Index	Payment Rate for Hospital-Based Facilities	Independent Facilities
1310	CAGUAS	0.9000	$45.05	$43.06
1320	CANTON	0.9814	$49.12	$46.95
1350	CASPER	1.0804	$54.07	$51.69
1360	CEDAR RAPIDS	0.9720	$48.65	$46.50
1400	CHAMPAIGN-URBANA-RANTOUL	1.0201	$51.06	$48.80
1440	CHARLESTON (SC)	0.9800	$49.05	$46.88
1480	CHARLESTON (WV)	1.0714	$53.62	$51.26
1520	CHARLOTTE-ROCK HILL	0.9460	$47.35	$45.26
1540	CHARLOTTESVILLE	1.0154	$50.82	$48.58
1560	CHATTANOOGA	1.0007	$50.09	$47.87
1580	CHEYENNE	0.9750	$48.80	$46.64
1600	CHICAGO	1.2148	$60.80	$58.12
1620	CHICO	1.1473	$57.42	$54.89
1640	CINCINNATI	1.0995	$55.03	$52.60
1660	CLARKSVILLE-HOPKINSVILLE	0.9000	$45.05	$43.06
1680	CLEVELAND	1.1915	$59.63	$57.00
1720	COLORADO SPRINGS	1.0710	$53.60	$51.24
1740	COLUMBIA (MO)	1.1585	$57.98	$55.42
1760	COLUMBIA (SC)	0.9592	$48.01	$45.89
1800	COLUMBUS (GA-AL)	0.9117	$45.63	$43.62
1840	COLUMBUS (OH)	1.0355	$51.83	$49.54
1880	CORPUS CHRISTI	0.9817	$49.13	$46.96
1900	CUMBERLAND	0.9133	$45.71	$43.69
1920	DALLAS	1.0426	$52.18	$49.88
1950	DANVILLE	0.9000	$45.05	$43.06
1960	DAVENPORT-MOLINE	1.0146	$50.78	$48.54
2000	DAYTON-SPRINGFIELD	1.1120	$55.66	$53.20
2020	DAYTONA BEACH	0.9056	$45.33	$43.32
2030	DECATUR (AL)	0.9000	$45.05	$43.06
2040	DECATUR (IL)	0.9851	$49.30	$47.13
2080	DENVER	1.2317	$61.65	$58.92
2120	DES MOINES	1.0581	$52.96	$50.62
2160	DETROIT	1.2200	$61.06	$58.36
2180	DOTHAN	0.9000	$45.05	$43.06
2200	DUBUQUE	1.0047	$50.29	$48.06
2240	DULUTH	0.9523	$47.66	$45.56
2290	EAU CLAIRE	0.9280	$46.35	$44.30
2320	EL PASO	0.9175	$45.92	$43.89
2330	ELKHART-GOSHEN	0.9356	$46.83	$44.76
2335	ELMIRA	1.0066	$50.38	$48.06
2340	ENID	0.9999	$47.06	$44.90
2360	ERIE	0.9879	$49.44	$47.26
2400	EUGENE-SPRINGFIELD	1.0198	$51.04	$48.79
2440	EVANSVILLE	1.0350	$51.80	$49.51
2520	FARGO-MOORHEAD	1.0292	$51.51	$49.24
2560	FAYETTEVILLE	0.9000	$45.05	$43.06
2580	FAYETTEVILLE-SPRINGDALE	0.9000	$45.05	$43.06
2640	FLINT	1.1951	$59.81	$57.17
2650	FLORENCE (AL)	0.9000	$45.05	$43.06
2655	FLORENCE (SC)	0.9000	$45.05	$43.06
2670	FORT COLLINS-LOVELAND	0.9811	$49.10	$46.94
2680	FT LAUDERDALE-POMPANO BEACH	1.0990	$55.06	$52.61
2700	FORT MYERS-CAPE CORAL	0.9447	$47.28	$45.19
2710	FORT PIERCE	0.9521	$47.65	$45.55
2720	FORT SMITH	0.9288	$46.49	$44.43
2750	FORT WALTON BEACH	0.9000	$45.05	$43.06
2760	FORT WAYNE	0.9340	[illegible]	[illegible]
2800	FORT WORTH-ARLINGTON	1.0132	[illegible]	$48.47
2840	FRESNO	1.2500	$60.38	$57.42

Payment Rate for

	MSA Name	Area Wage Index	Hospital-Based Facilities	Non-Hospital-Based Facilities	MSA Code	MSA Name	Area Wage Index	Hospital-Based Facilities	Non-Hospital-Based Facilities
1	GADSDEN	0.9190	$46.00	$43.96	4400	LITTLE ROCK-N LITTLE ROCK	1.0775	$53 [illegible]	$51 [illegible]
0	GAINESVILLE	0.9554	$47.82	$45.71	4420	LONGVIEW-MARSHALL	0.9000	$45 05	$43 06
2	GALVESTON-TEXAS CITY	1.1159	$55.70	$53.24	4440	LORAIN-ELYRIA	1.0375	$51 93	$49 63
0	GARY-HAMMOND	1.1254	$56.13	$53.84	4480	LOS ANGELES-LONG BEACH	1.2586	$64 [illegible]	$61 [illegible]
1	GLENS FALLS	0.9290	$46.50	$44.44	4520	LOUISVILLE	1.0412	$52 [illegible]	$49 81
3	GRAND FORKS	0.9548	$46.79	$44.72	4600	LUBBOCK	0.9473	$47 41	$45 32
3	GRAND RAPIDS	1.0208	$51.09	$48.84	4640	LYNCHBURG	0.9086	$45 48	$43 47
0	GREAT FALLS	0.9972	$49.71	$47.51	4680	MACON-WARNER ROBINS	0.9789	$48 99	$46 92
0	GREELEY	1.0400	$52.05	$49.75	4720	MADISON	1.0633	$53 [illegible]	$50 87
3	GREEN BAY	1.0190	$51.00	$48.75	4763	MANCHESTER-NASHUA	0.9747	$48 78	$46 63
1	GREENSBORO-WINSTON SALEM-HIGH	0.9433	$47.21	$45.13	4800	MANSFIELD	0.9283	$47 96	$45 85
0	GREENVILLE-SPARTANBURG	0.9333	$47.71	$45.61	4840	MAYAGUEZ	0.9000	$45 05	$43 06
1	HAGERSTOWN	1.0081	$50.46	$48.23	4880	MCALLEN-EDINBURG-MISSION	0.9000	$45 05	$43 06
0	HAMILTON-MIDDLETOWN	1.0509	$52.60	$50.28	4890	MEDFORD	1.0123	$50 67	$48 43
1	HARRISBURG-CARLISLE	1.0312	$51.61	$49.33	4900	MELBOURNE-TITUSVILLE	0.9542	$47 76	$45 63
1	HARTFORD-NEW BRITAIN-BRISTOL	1.1650	$58.31	$55.73	4920	MEMPHIS	1.0554	$52 82	$50 49
1	HICKORY	0.9000	$45.05	$43.06	4940	MERCED	1.1251	$56 31	$53 82
3	HONOLULU	1.1929	$59.70	$57.07	5000	MIAMI-HIALEAH	1.1255	$56 33	$53 84
1	HOUMA-THIBODAUX	0.9092	$45.51	$43.50	5015	MIDDLESEX-HUNTERDON	1.0510	$52 60	$50 28
0	HOUSTON	1.1000	$55.06	$52.62	5040	MIDLAND	1.0536	$52 73	$50 50
0	HUNTINGTON-ASHLAND	0.9524	$47.67	$45.56	5080	MILWAUKEE	1.0901	$54 56	$52 12
0	HUNTSVILLE	0.9000	$45.05	$43.06	5120	MINNEAPOLIS-ST PAUL	1.0768	$53 89	$51 51
1	INDIANAPOLIS	1.0568	$52.89	$50.56	5160	MOBILE	0.9294	$46 52	$44 46
3	IOWA CITY	1.0245	$51.27	$48.97	5170	MODESTO	1.1179	$55 95	$53 46
3	JACKSON (MI)	1.0419	$52.15	$49.84	5190	MONMOUTH-OCEAN	1.0136	$50 73	$48 49
0	JACKSON (MS)	0.9257	$46.33	$44.29	5200	MONROE	0.9332	$46 71	$44 64
0	JACKSON (TN)	0.9000	$45.05	$43.06	5240	MONTGOMERY	0.9531	$47 70	$45 62
1	JACKSONVILLE (FL)	0.9659	$48.34	$46.21	5280	MUNCIE	0.9783	$48 96	$46 80
1	JACKSONVILLE (NC)	0.9033	$45.22	$43.22	5320	MUSKEGON	0.9830	$49 20	$47 02
3	JAMESVILLE-BELOIT	0.9169	$45.89	$43.86	5345	NAPLES	0.9615	$48 12	$46 00
1	JERSEY CITY	1.1253	$56.32	$53.83	5360	NASHVILLE	1.0086	$50 [illegible]	$48 15
1	JOHNSON CITY-BRISTOL	0.9000	$45.05	$43.06	5380	NASSAU-SUFFOLK	1.2586	$64 [illegible]	$61 [illegible]
1	JOHNSTOWN	1.0196	$51.03	$48.78	5403	NEW BEDFORD-FALL RIVER-ATTLEB	0.9871	$49 40	$47 22
1	JOLIET	1.1709	$58.60	$56.02	5483	NEW HAVEN-WATERBURY-MERIDEN	1.1053	$55 33	$52 88
3	JOPLIN	0.9081	$45.45	$43.44	5523	NEW LONDON-NORWICH	1.0999	$55 05	$52 62
3	KALAMAZOO	1.0245	$51.29	$48.98	5560	NEW ORLEANS	0.9863	$49 38	$47 19
3	KANKAKEE	0.9674	$48.42	$46.28	5600	NEW YORK	1.2586	$64 [illegible]	$61 [illegible]
1	KANSAS CITY	1.0168	$50.89	$48.64	5640	NEWARK	1.1798	$59 05	$56 44
1	KENOSHA	1.1022	$55.16	$52.78	5700	NIAGARA FALLS	0.9563	$47 86	$45 77
3	KILLEEN-TEMPLE	0.9111	$45.60	$43.59	5720	NORFOLK-VIRGINIA BEACH-NEWPOR	0.9432	$47 21	$45 12
3	KNOXVILLE	0.9082	$45.31	$43.30	5775	OAKLAND	1.2586	$64 [illegible]	$61 [illegible]
1	KOKOMO	0.9998	$50.04	$47.83	5790	OCALA	0.9251	$46 30	$44 26
3	LA CROSSE	0.9710	$48.60	$46.45	5800	ODESSA	0.9423	$47 17	$45 09
3	LAFAYETTE (LA)	1.0005	$50.07	$47.85	5880	OKLAHOMA CITY	1.0049	$50 29	$48 05
3	LAFAYETTE (IN)	0.9219	$46.14	$44.10	5910	OLYMPIA	1.0139	$50 73	$48 49
0	LAKE CHARLES	0.9537	$47.73	$45.63	5920	OMAHA	1.0119	$50 63	$48 40
3	LAKE COUNTY	1.1843	$59.27	$56.75	5950	ORANGE COUNTY	1.0899	$54 54	$52 10
3	LAKELAND-WINTER HAVEN	0.9888	$49.49	$47.30	5960	ORLANDO	1.0899	$54 54	$52 10
0	LANCASTER	1.0636	$53.23	$50.89	5990	OWENSBORO	0.9888	$49 49	$47 30
3	LANSING-EAST LANSING	1.0728	$53.74	$51.37	6080	OXNARD-VENTURA	1.1272	$56 41	$53 91
0	LAREDO	0.9888	$49.49	$47.30	6015	PANAMA CITY	0.9888	$49 49	$47 30
0	LAS CRUCES	0.9888	$49.49	$47.30	6020	PARKERSBURG-MARIETTA	0.9687	$48 48	$46 34
0	LAS VEGAS	1.1782	$58.97	$56.37	6025	PASCAGOULA	1.0561	$52 86	$50 51
3	LAWRENCE	0.9879	$49.44	$47.26	6080	PENSACOLA	0.9162	$45 86	$43 84
0	LAWTON	0.9539	$47.74	$45.73	6120	PEORIA	1.0915	$54 62	$52 18
1	LEWISTON-AUBURN	0.9170	$45.90	$43.87	6160	PHILADELPHIA	1.1878	$59 45	$56 82
0	LEXINGTON-FAYETTE	0.9846	$49.28	$47.09	6200	PHOENIX	1.1150	$55 81	$53 31
3	LIMA	1.0182	$50.96	$48.71	6240	PINE BLUFF	0.9000	$45 05	$43 06
3	LINCOLN	0.9692	$47.51	$45.41	6280	PITTSBURGH	1.1301	$56 56	$54 06

Enclosure 2 Page 3

MSA Code	MSA Name	Area Wage Index	Payment Rate for Hospital-Based Facilities	Payment Rate for Independent Facilities
[illegible]	PITTSFIELD	1.0299	$51.55	$49.27
[illegible]	PONCE	0.9000	$45.05	$43.06
[illegible]	PORTLAND (ME)	1.0113	$50.62	$48.38
[illegible]	PORTLAND (OR)	1.1554	$57.83	$55.27
[illegible]	PORTSMOUTH-DOVER-ROCHESTER	0.9149	$45.79	$43.77
[illegible]	POUGHKEEPSIE	1.0710	$53.60	$51.24
[illegible]	PROVIDENCE-PAWTUCKET-WOONSOCK	1.0452	$52.31	$50.00
[illegible]	PROVO-OREM	0.9588	$47.99	$45.87
[illegible]	PUEBLO	1.0999	$55.05	$52.62
[illegible]	RACINE	0.9401	$47.05	$44.97
[illegible]	RALEIGH-DURHAM	1.0106	$50.58	$48.35
[illegible]	RAPID CITY	0.9249	$46.29	$44.25
[illegible]	READING	1.0154	$50.82	$48.58
[illegible]	REDDING	1.1361	$56.86	$54.35
[illegible]	RENO	1.2467	$62.40	$59.64
[illegible]	RICHLAND-KENNEWICK	0.9909	$49.59	$47.40
[illegible]	RICHMOND-PETERSBURG	0.9453	$47.31	$45.22
[illegible]	RIVERSIDE-SAN BERNARDINO	1.2327	$61.70	$58.97
[illegible]	ROANOKE	0.9569	$47.89	$45.78
[illegible]	ROCHESTER (MN)	1.0376	$51.93	$49.64
[illegible]	ROCHESTER (NY)	1.0433	$52.22	$49.91
[illegible]	ROCKFORD	1.0872	$54.41	$52.01
[illegible]	SACRAMENTO	1.2432	$62.22	$59.47
[illegible]	SAGINAW-BAY CITY-MIDLAND	1.1201	$56.06	$53.59
[illegible]	ST CLOUD	0.9407	$47.08	$45.00
[illegible]	ST JOSEPH	0.9953	$49.81	$47.62
[illegible]	ST LOUIS	1.0551	$52.81	$50.48
[illegible]	SALEM	1.0889	$54.50	$52.09
[illegible]	SALINAS-SEASIDE-MONTEREY	1.2419	$62.16	$59.41
[illegible]	SALT LAKE CITY-OGDEN	0.9764	$48.87	$46.71
[illegible]	SAN ANGELO	0.9000	$45.05	$43.06
[illegible]	SAN ANTONIO	0.9357	$46.83	$44.76
[illegible]	SAN DIEGO	1.2555	$62.84	$60.06
[illegible]	SAN FRANCISCO	1.2886	$64.49	$61.65
[illegible]	SAN JOSE	1.2886	$64.49	$61.65
[illegible]	SAN JUAN	0.9000	$45.05	$43.06
[illegible]	SANTA BARBARA-LOMPOC	1.1393	$57.02	$54.50
[illegible]	SANTA CRUZ	1.1707	$58.59	$56.01
[illegible]	SANTA FE	0.9465	$47.37	$45.28
[illegible]	SANTA ROSA-PETALUMA	1.2886	$64.49	$61.65
[illegible]	SARASOTA	0.9913	$49.61	$47.42
[illegible]	SAVANNAH	0.9446	$47.27	$45.18
[illegible]	SCRANTON-WILKES BARRE	1.0261	$51.36	$49.09
[illegible]	SEATTLE	1.0924	$54.67	$52.26
[illegible]	SHARON	0.9930	$49.70	$47.51
[illegible]	SHEBOYGAN	0.9354	$46.82	$44.75
[illegible]	SHERMAN-DENISON	0.9000	$45.05	$43.06
[illegible]	SHREVEPORT	1.0169	$50.90	$48.65
[illegible]	SIOUX CITY	1.0010	$50.10	$47.89
[illegible]	SIOUX FALLS	0.9630	$48.20	$46.07
[illegible]	SOUTH BEND-MISHAWAKA	0.9529	$47.69	$45.59
[illegible]	SPOKANE	1.1236	$56.24	$53.75
[illegible]	SPRINGFIELD (IL)	1.1007	$55.09	$52.66
[illegible]	SPRINGFIELD (MO)	0.9393	$47.01	$44.94
[illegible]	SPRINGFIELD (MA)	1.0203	$51.07	$48.81
[illegible]	STATE COLLEGE	1.1139	$55.75	$53.29
[illegible]	STEUBENVILLE-WEIRTON	0.9805	$49.07	$46.91
[illegible]	STOCKTON	1.2886	$64.49	$61.65
[illegible]	SYRACUSE	1.1852	$59.32	$56.70
8200	TACOMA	1.0853	$54.32	$51.92
8240	TALLAHASSEE	0.9481	$47.45	$45.36
8280	TAMPA-ST PETERSBURG-CLEARWATE	0.9972	$49.91	[illegible]
8320	TERRE HAUTE	0.9000	$45.05	$43.06
8360	TEXARKANA	1.0657	$53.34	$50.98
8400	TOLEDO	1.1759	$58.85	[illegible]
8440	TOPEKA	1.0723	$53.67	$51.32
8480	TRENTON	1.0670	$53.40	$51.05
8520	TUCSON	1.0333	$51.72	$49.43
8560	TULSA	1.0184	$50.97	$48.72
8600	TUSCALOOSA	1.0299	$51.55	$49.27
8640	TYLER	0.9950	$49.80	$47.60
8680	UTICA-ROME	0.9586	$47.98	$45.86
8720	VALLEJO-FAIRFIELD-NAPA	1.2886	$64.49	$61.65
8725	VANCOUVER	1.1388	$57.00	$54.48
8750	VICTORIA	0.9000	$45.05	$43.06
8760	VINELAND-MILLVILLE-BRIDGETON	1.0014	$50.12	$47.91
8780	VISALIA-PORTERVILLE	1.1989	$60.00	$57.36
8800	WACO	0.9047	$45.28	$43.28
8840	WASHINGTON	1.1931	$59.71	$57.08
8920	WATERLOO-CEDAR FALLS	0.9397	$47.03	$44.96
8940	WAUSAU	0.9288	$46.49	$44.35
8960	WEST PALM & DELRAY BEACH	0.9881	$49.45	$47.27
9000	WHEELING	0.9880	$49.45	$47.27
9040	WICHITA	1.0883	$54.47	$52.06
9080	WICHITA FALLS	0.9000	$45.05	$43.06
9140	WILLIAMSPORT	0.9553	$47.81	$45.70
9160	WILMINGTON (DE-NJ)	1.0890	$54.50	$52.10
9200	WILMINGTON (NC)	0.9239	$46.24	$44.20
9243	WORCESTER-LEOMINSTER	1.0000	$50.05	$47.85
9260	YAKIMA	0.9965	$49.87	$47.67
9280	YORK	1.0007	$50.09	$47.87
9320	YOUNGSTOWN-WARREN	1.1003	$55.07	$52.64
9340	YUBA CITY	1.0954	$54.82	$52.40

Payment Rate for

MSA Code	MSA Name	Area Wage Index	Essential-Renal Paralysis	Independent Facilities
AK Rural	ALASKA	1.4477	$72.46	$69.26
AL Rural	ALABAMA	0.9000	$45.05	$45.06
AR Rural	ARKANSAS	0.9000	$45.05	$45.06
AZ Rural	ARIZONA	0.9225	$46.17	$46.13
CA Rural	CALIFORNIA	1.0951	$54.81	$52.39
CO Rural	COLORADO	0.9130	$45.70	$45.68
CT Rural	CONNECTICUT	1.0747	$53.79	$51.41
DE Rural	DELAWARE	0.9244	$46.27	$46.22
FL Rural	FLORIDA	0.9053	$45.32	$45.22
GA Rural	GEORGIA	0.9000	$45.05	$45.06
HI Rural	HAWAII	1.1654	$58.33	$55.75
IA Rural	IOWA	0.9000	$45.05	$45.06
ID Rural	IDAHO	0.9052	$45.31	$45.30
IL Rural	ILLINOIS	0.9000	$45.05	$45.06
IN Rural	INDIANA	0.9000	$45.05	$45.06
KS Rural	KANSAS	0.9000	$45.05	$45.06
KY Rural	KENTUCKY	0.9000	$45.05	$45.06
LA Rural	LOUISIANA	0.9000	$45.05	$45.06
MA Rural	MASSACHUSETTS	1.0741	$53.76	$51.38
MD Rural	MARYLAND	0.9557	$47.83	$45.72
ME Rural	MAINE	0.9000	$45.05	$45.06
MI Rural	MICHIGAN	1.0118	$50.64	$48.40
MN Rural	MINNESOTA	0.9000	$45.05	$45.06
MO Rural	MISSOURI	0.9000	$45.05	$45.06
MS Rural	MISSISSIPPI	0.9000	$45.05	$45.06
MT Rural	MONTANA	0.9062	$45.36	$45.35
NB Rural	NEBRASKA	0.9000	$45.05	$45.06
NC Rural	NORTH CAROLINA	0.9000	$45.05	$45.06
ND Rural	NORTH DAKOTA	0.9024	$45.17	$45.17
NH Rural	NEW HAMPSHIRE	0.9945	$49.87	$47.67
NM Rural	NEW MEXICO	0.9226	$46.18	$46.14
NV Rural	NEVADA	1.0164	$50.87	$48.62
NY Rural	NEW YORK	0.9042	$45.26	$45.20
OH Rural	OHIO	0.9223	$46.16	$46.12
OK Rural	OKLAHOMA	0.9000	$45.05	$45.06
OR Rural	OREGON	1.0052	$50.31	$48.09
PA Rural	PENNSYLVANIA	1.0038	$50.19	$47.97
PR Rural	PUERTO RICO	0.9000	$45.05	$45.06
RI Rural	RHODE ISLAND	0.9478	$48.44	$46.30
SC Rural	SOUTH CAROLINA	0.9000	$45.05	$45.06
SD Rural	SOUTH DAKOTA	0.9000	$45.05	$45.06
TN Rural	TENNESSEE	0.9000	$45.05	$45.06
TX Rural	TEXAS	0.9000	$45.05	$45.06
UT Rural	UTAH	0.9202	$46.06	$46.02
VA Rural	VIRGINIA	0.9000	$45.05	$45.06
VT Rural	VERMONT	0.9000	$45.05	$45.06
WA Rural	WASHINGTON	0.9781	$48.95	$46.79
WI Rural	WISCONSIN	0.9000	$45.05	$45.06
WV Rural	WEST VIRGINIA	0.9178	$45.94	$43.91
WY Rural	WYOMING	0.9787	$48.88	$46.73

Enclosure 3

FACILITY INTEREST FORM

Please check one of the options below and return this form in the enclosed self-addressed envelope NO LATER THAN JANUARY 24, 1992, whether or not you are interested in the Demonstration.

_____ *My dialysis facility, identified below, is interested in providing staff to assist demonstration patients with home hemodialysis. We have patients who will be referred for eligibility review.*

_____ *My dialysis facility, identified below, is interested in providing staff to assist demonstration patients with home hemodialysis. At this time we do not have any patients to refer for eligibility review. If, during the demonstration period, we do have such patients, we will refer them for eligibility review.*

_____ *My dialysis facility is not interested in participating in this demonstration, for the following reasons. (Please provide complete reasons for lack of interest; this will be most helpful in HCFA's reports regarding response to this demonstration.):*

_____
_____
_____
_____

DIALYSIS FACILITY NAME: _____

ADDRESS: _____

_____

MEDICARE PROVIDER NUMBER: _____

_____ _____

DIALYSIS FACILITY ADMINISTRATOR'S SIGNATURE DATE

Appendix D -- Application Packet

APPLICATION PACKET

Contents:

- Three-page Physician Certification Statement
- One-page Patient Information and Consent Statement
- One-page Facility Certification Statement

Please photocopy and complete the entire set of application forms for each patient applying to enter the Demonstration.

Return all completed and signed application materials to your local ESRD Network

If you have questions, please call the project manager:
Andrea Hassol, Abt Associates Inc. (617)492-7100
between the hours of 9:00 and 5:00 Eastern Standard Time.

(Please complete ***for each patient*** applying to the Demonstration)

The Health Care Financing Administration (HCFA) is implementing and evaluating a Congressionally-mandated demonstration of staff-assisted home dialysis services. The purpose of the demonstration is to determine whether the services of home hemodialysis aides are cost-effective to the Medicare program and beneficial to selected patients.

To receive demonstration home aide services, ESRD patients must meet several eligibility requirements. For purposes of expediting the process of determining eligibility, HCFA is accepting a physician's statement as certification for three of these eligibility criteria.

1 - Patients must be confined to a bed or wheelchair and unable to transfer themselves from bed to chair. To certify that your patient meets this eligibility criterion, please place a check-mark next to the following statement:

The patient identified below is confined to a bed or wheelchair and is unable to independently transfer from bed to chair._____

2 - Patients must be eligible for ambulance transportation to receive routine maintenance dialysis treatments, in terms of medical necessity. For purposes of the demonstration, it is not necessary that the patient meet the destination requirement for Medicare-covered ambulance services to dialysis, i.e., the destination facility need not be hospital-based. The medical circumstances that necessitate ambulance transport must be expected to continue for at least six months. To certify that your patient meets this eligibility criterion, please place a check-mark next to the following statement:

My clinical assessment of this patient supports a determination that it is medically necessary for the patient identified below to be transported via ambulance for in-facility dialysis sessions and that this need for ambulance transport is expected to continue for at least six months._____

3 - Patients must have a medical condition that would be exacerbated by travel to a dialysis facility for routine maintenance dialysis. On the next page, HCFA has provided a list of Qualifying Medical Conditions that would meet this criterion. To certify that your patient meets this eligibility criterion, please check off ANY and ALL conditions that apply to your patient. (Please note that only patients whose medical condition is considered stable should be enrolled in the demonstration.) If your patient does not have one of the qualifying medical conditions listed, but another condition that you believe would be exacerbated by travel, please list that condition on page 3 and indicate how it would be exacerbated by travel.

Qualifying Medical Conditions

Serious medical conditions exacerbated by travel include conditions that: (a) would be exacerbated by travel in any vehicle except an ambulance; (b) make ambulance travel very onerous, harmful or potentially dangerous; (c) put patients at higher risk of further debilitation or decline in general physical or medical condition if the patient is regularly transported; (d) may not be serious singly but in combination constitute as large a general threat as a single more serious condition.

The patient identified below has one or more of the following medical conditions, which would likely be exacerbated by travel to routine maintenance dialysis.

___**Renal Osteodystrophy** or other advanced, degenerative bone disease, with incapacitation, severe pain, or history of fractures

___**Vertebral or other major fracture** not expected to be completely healed within six months

___**Bilateral amputation.** quadriplegia, paraplegia or other significant paralysis, in combination with decubitus ulcers. difficulty with bowel control, blindness, diabetes, cardiac or cardiovascular disease

___**Pulmonary diseases**/disorders requiring oxygen administration (patients with severe pulmonary disease potentially unstable during dialysis should not be enrolled)

___**Central nervous system disorders** involving symptoms of vertigo or syncopal episodes (patients who are seizure-prone should not be enrolled)

___**Severe arthritis** or hip problems, with incapacitation or severe pain

___**Carcinoma of the bone**

___**Need for continuous IV therapy**

___**Cardiac disease** with severe dyspnea or cardiac pain on mild exertion (patients with severe cardiac disorders that may be unstable during dialysis should not be enrolled)

___**Advanced age or fragility**

___**Morbid obesity** requiring assistance; malnourishment or rapid weight loss in recent past, resulting in generalized weakness, debilitation or incapacitation and requiring assistance

___**Mental or emotional disorder** such as fear of leaving the home, schizophrenia, depression or Alzheimer's disease

Alternatively, this patient has a medical condition that, although not appearing on the list of Qualifying Medical Conditions, makes travel problematic and potentially hazardous. This patient's relevant medical condition is:

_____

_____

_____

This condition is likely to be exacerbated by travel because:

_____

_____

_____

PATIENT NAME_____
(Last) (First) (Middle Initial)

PATIENT MEDICARE ID NUMBER_____

DATE OF ONSET OF ESRD_____

PHYSICIAN NAME_____
(Last) (First) (Middle Initial)

PHYSICIAN SIGNATURE_____

DATE_____

PATIENT INFORMATION AND CONSENT STATEMENT

I understand that, at present, home hemodialysis aide services are not paid for by Medicare. I agree to participate in the Staff-Assisted Home Dialysis demonstration in which I may receive a home hemodialysis aide paid for by Medicare. My participation is completely voluntary. I have discussed this demonstration with the staff of my dialysis facility and I understand the participation requirements.

I UNDERSTAND THAT IT IS POSSIBLE THAT NOT EVERYONE ELIGIBLE FOR DEMONSTRATION HOME HEMODIALYSIS AIDE SERVICES WILL ACTUALLY RECEIVE THESE SERVICES. If I am approved as eligible, a randomization process may place me in either an experimental group or in a control group. If selected for the experimental group, I will receive Medicare-covered home hemodialysis aide services. However, if selected for the control group, I will not receive the special Medicare-covered home hemodialysis aide services as provided under this demonstration.

I understand that I will participate in two interviews within a one-year period. I will be interviewed regardless of whether I am in the experimental or control group. The information that I provide in these interviews will be combined with factual information available in my medical care records. I understand that all information will be kept confidential and is covered by the U.S. Privacy Act of 1974.

I understand that to be eligible for home hemodialysis aide services, there must be no family member or friend who is available to assist me with home hemodialysis.

I have no family member or friend who is currently available to assist me with home hemodialysis.

PATIENT NAME _____
(Please print) **(Last)** **(First)** **(Middle Initial)**

PATIENT MEDICARE ID NUMBER _____

PATIENT PHONE NUMBER _____

PATIENT DATE OF BIRTH _____

PATIENT SOCIAL SECURITY NUMBER _____

PATIENT HOME ADDRESS _____

_____

_____ _____
PATIENT SIGNATURE **DATE**

FACILITY CERTIFICATION STATEMENT
(Please complete *for each patient* applying to the Demonstration)

In order to be eligible for the demonstration, patients must not be residing in a skilled nursing facility. In addition, it must be possible to install appropriate hemodialysis and water treatment equipment in the patient's home.

To my knowledge, the patient identified below is not residing in a skilled nursing facility.

To my knowledge, this patient's home is suitable for hemodialysis and water treatment equipment.

I have discussed the demonstration with this patient. I believe that s/he understands the demonstration, including the chance that s/he will be randomized into a control group and not receive a Medicare-paid home aide.

PATIENT NAME_____
(Last) **(First)** **(Middle Initial)**

PATIENT MEDICARE ID NUMBER_____

DIALYSIS FACILITY NAME_____

DIALYSIS FACILITY ADDRESS_____

_____

MEDICARE FACILITY PROVIDER NUMBER_____

_____ _____
DIALYSIS FACILITY ADMINISTRATOR'S SIGNATURE **DATE**

Appendix E -- Patient Status

Enrollment Status

Pat #	Net	Unit	as of 1/1/95 W/D	Died	Alive	Rec'd Aide	Treatment Grp Exp.	Control	Study Start Date
1	2	A			+	-	E		22 Dec. 93
2	2	A		+		-		C	5 Jan. 94
3	2	B		+		-	E		14 May. 92
4	2	B	+			-		C	21 Jul. 93
5	3	C		+		-	E		8 Nov. 93
6	4	D		+		-	E		9 Apr. 92
7	4	D		+		-		C	9 Apr. 92
8	4	D	+			-	E		9 Apr. 92
9	4	D		+		-		C	14 May. 92
10	4	D		+		Y	E		8 Jun. 92
11	4	D	+			-		C	24 Jul. 92
12	4	D		+		-		C	29 Dec. 92
13	4	D		+		Y	E		11 Jan. 93
14	4	D		+		Y	E		19 Jan. 93
15	4	D			+	-		C	16 Mar. 93
16	4	D		+		Y	E		31 Mar. 93
17	4	D		+		-		C	21 Jul. 93
18	4	D			+	Y	E		6 Oct. 93
19	4	E	+			-	E		23 Feb. 94
20	4	F		+		Y	E		9 Apr. 92
21	4	F		+		-		C	5 May. 93
22	4	F			+	Y	E		25 Oct. 93
23	4	F		+		-		C	26 Jan. 94
24	4	F		+		-		C	26 Jan. 94
25	4	F		+		Y	E		15 Mar. 94
26	4	F			+	-		C	17 Mar. 94
27	4	F		+		-	E		7 Apr. 94
28	4	F		+		-	E		7 Apr. 94
29	4	F		+		-		C	25 Apr. 94
30	4	G		+		Y	E		9 Apr. 92
31	4	G		+		-		C	14 May. 92
32	4	G		+		-		C	5 Jan. 93
33	4	G		+		-	E		23 Jan. 93
34	4	H		+		-		C	9 Apr. 92
35	5	I		+		-		C	9 Apr. 92
36	5	J		+		-	E		9 Apr. 92
37	5	K		+		-		C	8 Jun. 93
38	5	K		+		-		C	8 Jun. 93
39	5	K		+		-		C	8 Jun. 93
40	5	K		+		-	E		8 Jun. 93
41	5	K		+		Y	E		8 Jun. 93
42	5	K		+		Y	E		8 Jun. 93
43	5	K		+		Y	E		8 Jun. 93
44	5	K		+		-		C	8 Jun. 93
45	5	K		+		-		C	8 Jun. 93
46	5	K			+	Y	E		8 Jun. 93

			as of 1/1/95			Rec'd	Treatment Grp		Study
Pat #	Net	Unit	W/D	Died	Alive	Aide	Exp.	Control	Start Date
47	5	L		+		-	E		22 Apr, 93
48	5	M		+		-		C	14 Apr, 92
49	5	M	+			-	E		30 Nov, 92
50	7	N	+			-	E		9 Apr, 92
51	7	O		+		-		C	14 Apr, 92
52	7	P		+		-	E		14 Apr, 92
53	8	Q		+		Y	E		14 Apr, 92
54	8	Q			+	Y	E		14 Apr, 92
55	8	Q		+		-		C	14 Apr, 92
56	8	Q			+	-		C	14 Apr, 92
57	10	R		+		-		C	30 Nov, 92
58	10	S		+		-		C	14 Apr, 92
59	10	S		+		Y	E		14 Apr, 92
60	10	S		+		-		C	14 Apr, 92
61	11	T			+	-	E		29 Apr, 94
62	12	U			+	-	E		20 Apr, 94
63	12	V		+		Y	E		4 May, 92
64	12	V			+	-		C	4 May, 92
65	12	Q			+	-		C	11 Aug, 93
66	13	X	+			-	E		9 Apr, 92
67	13	X	+			-		C	9 Apr, 92
68	13	X			+	-		C	9 Apr, 92
69	13	Y	+			-	E		9 Apr, 92
70	13	Y		+		-		C	9 Apr, 92
71	13	Y		+		-		C	9 Apr, 92
72	13	Y		+		-	E		9 Apr, 92
73	14	Z		+		-		C	20 Aug, 92
74	15	A'		+		Y	E		27 Jul, 92
75	15	B'		+		-	E		21 May, 92
76	15	C'			+	-		C	13 Sep, 93
77	15	D'		+		-		C	14 Oct, 93
78	15	E'	+			-	E		2 Jun, 92
79	15	E'		+		-		C	2 Jun, 92
80	15	E'	+			-	E		2 Jun, 92
81	15	E'		+		-		C	2 Oct, 92
82	15	F'	+			-	E		4 May, 93
83	15	F'		+		-		C	4 May, 93
84	16	G'		+		-		C	14 May, 92
85	16	G'	+			-	E		14 May, 92
86	16	H'		+		-		C	8 Jun, 92
87	16	I'			+	Y	E		9 Apr, 92
88	18	J'	+			-		C	12 Oct, 93
89	18	K'		+		-		C	9 Apr, 92
90	18	L'			+	-	E		4 Feb, 94
91	18	L'			+	Y	E		Apr, 92